AMENDED EXHIBIT E

Part 1

Summary of Key Karen Frank Testimony

Karen Frank was the PSC's expert on pharmacovigilance. That is the specialty of evaluating complaints made by hospitals, doctors, and patients about a drug (adverse event reports) to assess whether they signal a problem with the product. Her role was to comment on the adequacy of Actavis' pharmacovigilance process and any signal detection for Digitek®. (K. Frank dep. @ 70).

As a starting place, the FDA has never found that there was a signal of problems with Digitek®. Despite Form 483s and warning letters on other regulatory issues, there are none on this topic. In 2009, on its website, the FDA specifically discussed the Digitek® recall and said:

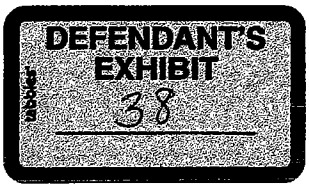
> Since the detection of the manufacturing problem, FDA has been actively engaged with this company to ensure that **ALL** potentially affected amounts of Digitek® tablets have been recalled. In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely.

See "Facts and Myths About Generic Drugs," July 9, 2009, FDA website, available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm, attached hereto.

If Actavis produced substantial quantities of defective Digitek®, there would have been an unusual number of cases of digoxin toxicity somewhere in the United States. The Plaintiffs' general causation expert, Dr. Semigran, was unaware of any reported literature from any source saying there was. See M. Semigran dep. @ 23; see also D. Bliesner dep. @ 207-208; J. Farley dep. @ 368-369; M. Kenny dep. @180; D. Nelson @ 29, 54.

So, did Karen Frank find some hidden signal in the adverse event reporting data that Actavis supposedly ignored? No.

First, she did not even come up with her own opinions. The PSC told her what they wanted, and she tried to support it. (K. Frank dep. @ 247-250). Second, despite being asked about signal detection, the PSC did not give her any information that would allow her to perform such an analysis. (K. Frank dep. @ 70, 72-74). Third, in her view, while the PSC spent "lots" of time in deposition with Actavis company witnesses on general regulatory compliance issues, there was little specific to Digitek®. She was, therefore, "unable to subset out information on the systems specifically for Digitek®." (K. Frank dep. @ 17-20). Fourth, because of the first three issues, Dr. Frank became very concerned about whether her "opinions" were even supported by sufficient data. (K. Frank dep. @ 83-85). Finally, as a result, she did not even fully stand by her report. (K. Frank dep. @ 219-221).



FDA U.S. Food and Drug Administration

Drugs

Facts and Myths about Generic Drugs

Today, 7 in 10 prescriptions filled in the United States are for generic drugs. This fact sheet explains how generic drugs are made and approved and debunks some common myths about these products.

FACT: FDA requires generic drugs to have the same quality and performance as the brand name drugs.

- When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity and potency. Some variability can and does occur during manufacturing, for both brand name and generic drugs. When a drug, generic or brand name, is mass produced, very small variations in purity, size, strength and other parameters are permitted. FDA puts limits on how much variability in composition or performance of a drug is acceptable.
- Generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name (or reference) product. Generic drugs do not need to contain the same inactive ingredients as the brand product.
- Through review of bioequivalence data, FDA assures that the generic product will perform the same as its respective brand name (or reference product. This standard applies to all generic drugs, whether immediate or controlled release.
- A generic drug must be shown to be bioequivalent to the reference drug; that is, it must be shown to give blood levels that are very similar to those of the reference product. If blood levels are the same, the therapeutic effect will be the same. In that case, there is no need to carry ou a clinical effectiveness study and they are not required.
- All generic manufacturing, packaging and testing sites must pass the same quality standards as those of brand name drugs and the generic products must meet the same exacting specifications as any innovator brand name product. In fact, many generic drugs are made in the sam plants as innovator brand name drug products.
- If an innovator of a brand name drug switches drug production to an alternative manufacturing site, or they change formulation of their brand name drug, these companies are held to the same rigorous manufacturing requirements as those that apply to generic drug companies.

FACT: Research shows that generics work just as well as brand name drugs.

- A recent study evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand-name counterparts. There was no evidence that brand-name heart drugs worked any better than generic heart drugs. [Kesselheim et al. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21) 2514-2526].

FACT: When it comes to price, there is a big difference between generic and brand name drugs. On average, the cost of a generic drug is 80 to 85% lower than the brand name product.

- An IMS National Prescription Audit shows that a typical formulary now charges $6 for generic medications, $29 for preferred branded drugs, and $40 or more for non-preferred branded drugs. [Aitken et al. Prescription drug spending trends in the United States: looking beyond the turning point. Health Aff (Millwood). 2009;28(1):w151-60].
- Independent research has shown that total prescription drug expenditures in the United States only increased by 4.0% from 2006 to 2007, wit total spending rising from $276 billion to $287 billion. This is a sharp decrease from the 8.9% growth rate observed in prescription drug expenditures in 2006. One factor cited as a reason for the slowdown is an increase in availability and use of generic drugs [Hoffman et al. Projecting future drug expenditures--2009. Am J Health Syst Pharm. 2009;66(3):237-57].

Recently, some misinformation has raised concerns over generic drugs. Below are some common myths in circulation.

MYTH: FDA lets generic drugs differ from the brand name counterpart by up to 45 percent.

FACT: This claim is false. Anyone who repeats this myth does not understand how FDA reviews and approves generic drugs.

- FDA recently evaluated 2,070 human studies conducted between 1996 and 2007. These studies compared the absorption of brand name and generic drugs into a person's body. These studies were submitted to FDA to support approval of generics. The average difference in absorption into the body between the generic and the brand name was **only 3.5 percent** [Davit et al. Comparing generic and innovator drugs: a review c 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother. 2009;43(10):1583-97]. Some generics were absorbed slightly more, some slightly less. This amount of difference would be expected and acceptable, whether for one batch of brand name drug tested against another batch of the same brand, or for a generic tested against a brand name. In fact, there have been studies in which branded drugs were compared with themselves as well as with a generic. As a rule, the difference for the generic-to-brand comparison was about the same as the brand-to-brand comparison.
- Any generic drug modeled after a single, brand name drug (the reference) must perform approximately the same in the body as the brand name drug. There will always be a slight, but not medically important, level of natural variability – just as there is for one batch of brand name drug to the next.

MYTH: People who are switched to a generic drug are risking treatment failure.

FACT: There is no evidence for this claim. Treatment failures can and do occur when taking generic or brand name drugs. If someone is switched to a generic drug around the time they are relapsing, they may attribute the problem to the switch.

- Many people who have recovered from major depression have a relapse despite continued treatment. These relapses have been shown in trials of long-term therapy. [Byrne and Rothschild. Loss of antidepressant efficacy during maintenance therapy: possible mechanisms and treatments. J Clin Psychiatry. 1998;59(6):279-88].
- Many people who are on a seizure medications will re-experience a seizure despite continued treatment. [Randomised study of antiepileptic drug withdrawal in patients in remission. Medical Research Council Antiepileptic Drug Withdrawal Study Group. Lancet. 1991;337(8751):1175-80].
- A percentage of people will re-experience gastric ulcers, despite an initial, positive response to and continued treatment with prescription strength antacids (cimetidine tablets; http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=8131#nlm34067-[1]9).

MYTH: Generic drugs cost less because they are inferior to brand name drugs.

FACT: Generic manufacturers are able to sell their products for lower prices, not because the products are of lesser quality, but becaus generic manufacturers generally do not engage in costly advertising, marketing and promotion, or significant research and development.

- When a brand name drug comes off patent and generic drugs are permitted to compete with the brand name drug, the generic products compete by offering lower prices. Unlike the manufacturers of brand name drugs, generic drug companies do not have significant expenses to recoup for advertising, marketing and promotion, or research and development activities.

MYTH: There are quality problems with generic drug manufacturing. A recent recall of generic digoxin (called Digitek) shows that generic drugs put patients at risk.

FACT: FDA's aggressive action in this case demonstrates the high standards to which all prescription drugs – generic and brand name - are held.

- In March 2008, FDA performed a scheduled inspection of the Actavis production facility and identified products that were not manufactured to required specifications over a period of time extending back to the year 2006. Included in this list of products was one particular lot of Digitek.
- Actavis detected a very small number of oversized tablets in this lot (specifically, 20 double-sized tablets in a sample of approximately 4.8 million tablets).
- Although Actavis attempted to remove the affected Digitek tablets through visual inspection, FDA determined that this method of removal was inadequate to assure the product's quality and consistency in accordance with the current Good Manufacturing Practice (cGMP) regulations.
- Since the detection of the manufacturing problem, FDA has been actively engaged with this company to ensure that **ALL** potentially affected lots of Digitek tablets have been recalled. In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely.
- FDA takes action whenever we find that a drug manufacturer is not following cGMPs. Over the last ten years, FDA has taken enforcement action against many brand name and generic firms for failing to meet FDA manufacturing quality standards.

MYTH: FDA's enforcement action against the generic drug company Ranbaxy demonstrates quality problems with imported generic drugs.

FACT: FDA's action demonstrates FDA's commitment to safe generic drugs.

- FDA has taken several regulatory actions against the generic drug manufacturer Ranbaxy, on the basis of problems at two of Ranbaxy's manufacturing facilities. Ranbaxy is one of many non-U.S. based generic and brand drug manufacturers.
- On Sept. 2008, the FDA issued two warning letters and instituted an Import Alert barring the entry of all finished drug products and active pharmaceutical ingredients from Ranbaxy's Dewas, Paonta Sahib and Batamandi Unit facilities due to violations of U.S. cGMP requirements. That action barred the commercial importation of 30 different generic drugs into the United States and remains in effect today (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149532.htm[2]).
- Subsequent FDA investigations also revealed a pattern of questionable data raising significant questions regarding the reliability of certain generic drug applications from Ranbaxy.
- To address the allegedly falsified data, the FDA has invoked its Application Integrity Policy (AIP) against the Paonta Sahib facility. When the AIP is implemented, the FDA stops all substantive scientific review of any new or pending drug approval applications that contain data generated by the Paonta Sahib facility. This AIP covers applications that rely on data generated by the Paonta Sahib facility only.
- In the fiscal year 2008, FDA performed 2,221 drug-related inspections. FDA takes many different enforcement actions, not just against generic drug manufacturers. For a list of enforcement actions in the fiscal year 2008, see http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129812.pdf[3]. It is FDA's responsibility to ensure that the drugs people use, generic or brand name, are safe and effective.

MYTH: Brand name drugs are safer than generic drugs.

FACT: FDA receives very few reports of adverse events about specific generic drugs. Most reports of adverse events are related to side effects of the drug ingredient itself.

- The monitoring of postmarket adverse events for all drug products, including generic drugs, is one aspect of the overall FDA effort to evaluate the safety of drugs after approval. In most cases, reports of adverse events generally describe a **known reaction** to the active drug ingredient.

MYTH: FDA does not care about concerns over generic drugs.

FACT: FDA is actively engaged in making all regulated products – including generic drugs – safer.

- We are aware that there are reports noting that some people may experience an undesired effect when switching from brand name drug to a generic formulation or from one generic drug to another generic drug. Evidence indicates that if problems with interchangeability of drug formulations occur, they occur only for a very small subset of people.
- FDA is encouraging the generic industry to investigate whether, and under what circumstances, such problems occur. The Agency does not have the resources to perform independent clinical studies, and lacks the regulatory authority to require industry to conduct such studies. FDA will continue to investigate these reports to ensure that it has all the facts about these treatment failures and will make recommendations to healthcare professionals and the public if the need arises.

Links on this page:

1. http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=8131#nlm34067-
2. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149532.htm
3. http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129812.pdf

Volume: I
Pages: 1-132
Exhibits: See Index

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
MDL CASE NO. 2:09-cv-121
MDL 1968

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

* * * * * * * * * * * * * * * * * * * *

BOBBY R. MILLIGAN, ET AL., :
PLAINTIFFS :
:
v. :
:
ACTAVIS GROUP HF, ET AL., :
DEFENDANTS :

* * * * * * * * * * * * * * * * * * * *

DEPOSITION OF MARC J. SEMIGRAN, M.D., a witness called on behalf of the Defendant, Actavis Group, HF, pursuant to the provisions of the Federal Rules of Civil Procedure, before Lisa McDonald Valdario, (CSR #130093), a Registered Professional Reporter and Notary Public in and for the Commonwealth of Massachusetts, held at the Holiday Inn Boston at Beacon Hill, 5 Blossom Street, Boston, Massachusetts 02114, on Wednesday, June 23, 2010, commencing at 10:04 a.m.

with some number of people, right?
A Correct.
Q Did you ever do any study of the Mass. General statistics to see if there was any spike in diagnoses of digoxin toxicity in 2005, 6, 7 or 8?
A Did not.
Q Are there people at Mass. General who watch for trends like that?
A There is a quality assurance program. I am not sure. I do not know if that's one of their charges.
Q Well, given your administrative positions and your clinical positions, if there had been some spike in the diagnoses of digoxin toxicity in those years, do you think that's something that would have come to your attention?
A I can only say possibly. It's a large organization, and often times there are things I think should have come to my attention earlier than they do, that I eventually find out about, so.

There are probably things that I might think should come to my attention that do not.
Q Your CV, because of its length, was a bit much to get through all the publications. Have you ever

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

MDL NO: 1968

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION,

_____/

100 N. Tampa Street
Suite 2900
Tampa, FL 33602
February 18, 2011
at 8:15 a.m.

VIDEOTAPE DEPOSITION OF DAVID BLIESNER, Ph.D.

Taken on behalf of the Defendants before PHILIP RYAN, RPR, Court Reporter, Notary Public in and for the State of Florida at Large, pursuant to Defendant's Notice of Taking Deposition in the above cause.

a specific problem? I'm sorry a specific product. 01:52

A. Well, I don't work for the FDA and I'm not going to speak for the FDA, but if they find -- go back look at the EIRs and see that there are all kinds of problems with respect to manufacturing records and lack of manufacturing records, validated processes and things like that. So that's what they do. 01:52

They put -- if the question as to the integrity of the manufactured product, then, you know, they take action. 01:52

Q. What question were you just answering? I move to strike that as completely non-responsive. 01:52

Were you talking about Activis or their records somehow? 01:52

A. I'm talking about the records that the FDA reviewed and their systems and places that will show up on the establishment inspection report. 01:52

Q. Are you an expert in GMP compliance or not? 01:53

A. Am I am, sir. 01:53

Q. Okay. I'm asking you a question about 01:53

FDA practice that ought to be right down the middle of that expertise. I don't know why you don't want to answer it, but -- I know exactly why you don't want to answer it but I'm going to keep asking it until you do. 01:53

MR. KERENSKY: Objection, form. 01:53

BY MR. ANDERTON: 01:53

Q. Okay. How would the FDA -- let's assume, Dr. Bliesner, that the FDA was doing an inspection and uncovered a GMP practice that they believed was deficient. 01:53

A. Okay. 01:53

Q. That happens; right? 01:53

A. Yes, it does. 01:53

Q. That's what you charge your clients to assess; right? 01:53

A. Yes. 01:53

Q. If the FDA wanted to determine whether that GMP deficiency impacted a particular product, how would they do that? 01:53

A. They may or may not start looking at all of the quality systems that are in there. I'm just telling you how they do it. They could stop when they see significant deficiencies and there is doubt in their mind they just stop. That's 01:54

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

MDL NO. 1968

VOLUME II

The continued videotaped deposition of JAMES J. FARLEY taken by counsel for the Defendants, Actavis Totowa, LLC, Actavis, Inc., and Actavis Elizabeth, LLC, pursuant to notice and by agreement of counsel, reported by Angela S. Garrett, CSR, RPR, B-2407, at the Embassy Suites, 145 Mulberry Boulevard, Savannah, Georgia, on January 19, 2011, commencing at 9:03 a.m.

Q How about 483s?
A Yes.
Q Warning letters?
A Yes.
Q Recalls?
A Yes.
Q Have you seen any -- have you -- I'm sorry. Let me rephrase that.
Have you been provided with any scientific information whatsoever that there was a spike in Digoxin toxicity at hospitals, nursing homes, poison control centers or outpatient facilities in -- at any point between 2005 and 2008?
A I'm not sure what you mean by Digoxin toxicity.
Q Do you have any idea what that means?
A You mean OD, overdosing, or too much strength? I mean, Digoxin when used properly is not toxic. And to say Digoxin toxicity, if you mean over-strength tablets -- I'm not -- let me not put words -- please tell me again.
Q Digoxin toxicity simply for the purpose of my question is somebody who has a toxic reaction to Digoxin, whether the -- regardless of what the dose is. Okay?

What I'm asking you is whether you've been provided with any scientific proof that there was a spike in Digoxin toxicity at any sort of medical facility in the United States between 2005 and 2008.

A No.

MR. ERNST: I'm going to object, vague, ambiguous, calls for speculation.

MR. KERENSKY: When you get to a breaking point I'd like to take a break.

MR. ERNST: Scientific proof is not a standard.

MR. MORIARTY: Now is fine.

THE VIDEOGRAPHER: Okay. We're going off the --

MR. MORIARTY: Mike wants to take a break, Don. So we're going to do that.

THE VIDEOGRAPHER: Going off record. This is the end of Tape No. 1. 9:55.

(A brief recess was taken.)

THE VIDEOGRAPHER: Okay. We're back on record. It's 10:11 and this is the beginning of Media Unit No. 2.

BY MR. MORIARTY:

Q Mr. Farley, this is Exhibit 57 from your first deposition. This is a Form 483, is it not?

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
MDL No. 1968

IN RE:
DIGITEK PRODUCT
LIABILITY LITIGATION

VIDEOTAPED
DEPOSITION OF:
MARK G. KENNY
VOLUME I

- - - - - - - - - - - -

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before CAROL ANN SHEPARD, a Certified Court Reporter of the State of New Jersey, held at the MARRIOTT NEWARK AIRPORT HOTEL, 1 Hotel Road, Newark, New Jersey, on Tuesday, June 29, 2010, commencing at 8:30 in the forenoon.

do with the information.

Q. Have you read the depositions of any doctors --

A. No.

Q. -- who have been taken in this case?

A. No. I have no interest.

Q. Do you know from any independent research whether any hospital reported an increased incidence of Digoxin toxicity in the years 2005, '06, '07 or '08?

A. I did no investigation of any sort, so the answer is I know of nothing, because I didn't do anything.

Does that make sense?

Q. All right. Let me get back to some statistics that I was asking you about before.

Of this 688.2 million tablets that were part of the recall, do you have any opinion, to a reasonable probability, as to what percentage of them were outside the USP specifications on the low side?

A. On the low side?

I have no way of knowing that.

Q. Do you have any opinion, to a probability, of what percentage of those tablets

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

* * *

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION MDL NO. 1968

* * *

Deposition of EJORN D. NELSON, PHARM.D., Witness herein, called by the Defendants for cross-examination pursuant to the Rules of Civil Procedure, taken before me, Mary Jo Stevens, a Notary Public in and for the State of Ohio, at the Doubletree Cincinnati Airport, 2826 Terminal Drive, Hebron, Kentucky, on Tuesday, the 22nd day of June, 2010, at 8:22 a.m.

* * *

thing as official consulting privileges. What I know is that since 1972 physicians from that hospital and other hospitals routinely ask for and receive a consultation and advice from me and other specialists in toxicology at the poison center.

Q. Do you officially take call at any hospitals?

A. No.

Q. Have you ever studied any of the University of Cincinnati Medical Center statistics to see if there was a spike in complaints about digoxin any time between 2005 and the first half of 2008?

A. No.

Q. In looking at Exhibit 41, your CV, I did not see that any of the articles that you published were directly about digoxin. Were there any?

A. Yes.

Q. Tell me which ones are directly about digoxin.

A. Okay. Page nine, number three.

Q. Let's stop there for a second. Does that just have a section about digoxin --

reactions. If you give a drug and something peculiar happens at the same time, you have a high index of suspicion that giving the medication might have had something to do with it. It is a complex judgment-heavy area of undertaking and it requires some experience and knowledge of the patient's pathophysiologic condition and the effects of the medication -- of medications that the patient is taking.

Q. And you certainly want to rule out other potential factors of the adverse event, correct?

A. If possible, yes.

Q. I asked you before whether you had studied the University of Cincinnati's statistics and whether they had had a spike of digoxin. Did you do any study like that at the poison center?

A. No.

Q. Do you know how many calls the poison center received after the April 25th recall regarding Digitek?

A. I do not.

Q. Do you know how many calls the poison center received prior to April 25th,

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT
LIABILITY LITIGATION

MDL NO. 1968

Videotaped deposition of KAREN A. FRANK, M.D., taken at the law offices of SEGAL McCAMBRIDGE SINGER & MAHONEY, LTD., 1818 Market Street, Suite 2600, Philadelphia, Pennsylvania, on Wednesday, June 30, 2010, commencing at 9:10 a.m., before Dianna R. Pugliese, a Registered Merit Reporter, Certified Realtime Reporter, Certified Shorthand Reporter (NJ & DE), and Notary Public, pursuant to notice.

APPEARANCES
FOR THE PLAINTIFF:
Mr. Fred Thompson, III
Motley Rice LLC
28 Bridgeside Boulevard
Mount Pleasant, South Carolina 29464
843-216-9118

FOR THE DEFENDANTS:
Mr. Richard A. Dean
Tucker Ellis & West LLP
1150 Huntington Building
925 Euclid Avenue
Cleveland, Ohio 44115-1475
216-696-2137

Ms. Monee A. Takla
Tucker Ellis & West LLP
515 South Flower Street, 42nd Floor
Los Angeles, California 90071
213-430-3378

Mr. Harvey L. Kaplan
Shook, Hardy & Bacon, LLP
255 Grand Boulevard
Kansas City, Missouri 64108
816-474-6550

ALSO PRESENT:
David Williams, Video Operator

EXAMINATION INDEX

EXHIBIT INDEX

COURT REPORTER: Are there any stipulations for the record?
MR. DEAN: No.
VIDEO OPERATOR: We're now on the video record.
This is the videotape deposition of Karen A. Frank, M.D., taken by the Defendant, In Re: Digitek Product Liability Litigation, in the United States District Court for the Southern District of West Virginia, Charleston Division, held at the offices of Segal McCambridge Singer & Mahoney, Ltd., 1818 Market Street, Philadelphia, Pennsylvania, on Wednesday, June 30, 2010.
The time is 9:10 a.m.
I am David Williams, the videographer. The court reporter is Dianna Pugliese. We are from the firm of Rennillo Court Reporting in Cleveland, Ohio.
Counsel, will you now please introduce yourselves.
MR. DEAN: My name is Richard Dean. I represent the Actavis defendants.
MS. TAKLA: Monee Takla for the Actavis defendants.
MR. KAPLAN: Harvey Kaplan, Shook, Hardy

& Bacon, for Mylan.
MR. THOMPSON: Fred Thompson, Motley Rice, for Plaintiffs.
VIDEO OPERATOR: The reporter will now swear in the witness.
KAREN A. FRANK, M.D., having been duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. DEAN:
Q. Good morning.
A. Good morning.
Q. Would you state your full name for the record, please?
A. Karen Ann Frank.
Q. And it's Dr. Frank; correct?
A. Yes.
Q. Dr. Frank, we met before, but my name is Richard Dean.
Have you ever had your deposition taken before?
A. No.
Q. So this is your very first deposition ever; correct?
A. Yes.
Q. Have you ever testified in a court in

Page 6

front of a jury before?
A. No.
Q. Has Mr. Thompson or someone else on behalf of the plaintiffs had a chance to tell you about the deposition process a little bit?
A. Yes.
Q. Okay. Well, let me just go over a few ground rules.
I'm going to be asking you some questions today, so it's very important that the two of us communicate. So if I ask you a question that you do not understand, will you tell me that?
A. Yes.
Q. Your responses have to be verbal, out loud. We can't -- this court reporter, at least, can't take the shaking or nodding of the head in a particular direction.
So will you speak up and use whatever words you want to use, but please speak up and give your answer verbally?
A. Yes.
Q. And I understand you're not -- you're a little bit under the weather today?
A. Yes.
Q. At any point if you need a break for any

Page 7

reason, just let us know and we'll take a break. Okay.
A. Uh-huh.
Q. Yes?
A. Yes.
Q. What have you done to prepare for the deposition today?
A. I was sent a set of volumes of printed material. I went through them generally, and then I went through them looking for white space or blanks with information that I thought should be there that was not there.
I met with Pete Miller and Megan Carter over lunch, and I presented them with a list of documents that I would liked to have seen, and they referenced it against what was available in discovery and they sent me two more printed volumes, electronic copies of everything I had electronic copies of.
And then one final Establishment Inspection Report.
MR. KAPLAN: One final what?
THE WITNESS: Establishment Inspection Report.
BY MR. DEAN:
Q. My question was, what you did to get --

Page 8

not to write the report, but to get ready for the deposition.
What is it that you did to get ready for the deposition today?
A. I reread these two documents yesterday.
Q. And by these two documents, for the record, you are referring to what I've marked already as Defendant's Exhibits 49 and 50; is that correct?
A. Yes. I went back and reviewed to refresh my memory.
Q. Well, actually, 40 -- just so we're clear, 49 is a copy of your resume; correct?
A. No.
Q. No?
A. This -- what I reviewed was a copy of the Conclusion.
Q. Right.
A. And I went through this document. I can't say that I went through it a hundred percent. I went through key sections where I wanted to refresh my memory.
Q. And for the record, what you have is the long document we've marked as Exhibit 50 to this deposition; is that correct?
A. Yes.

Page 9

Q. And I compared them before. Your document has 70 pages and Exhibit 50 also has 70 pages, so they are the same.
A. There should be no alterations between what you received and what I printed.
Q. So what you did in preparation for the deposition was to review what we marked as Exhibit 50; correct?
A. I don't know why this is not marked as an exhibit, because this is the key opinion. This was at one point one document. And at the request of Pete Miller, it was split. So he asked me to address two separate issues --
Q. Let me just interrupt. I won't do that often, but I want to make sure we get this exhibit marked correctly.
The shorter document that you have in front of you is -- are you telling me that's not included in Exhibit 50?
A. Yes. It is not included in Exhibit 50.
Q. Okay. Can I see it, please?
A. Yes. (Document provided.)
Q. Dr. Frank, I have just reviewed the first 11 pages of Exhibit 50 and it -- it would -- those first set of pages would appear to be exactly

Page 10

what is in the shorter document.
A. Okay.
Q. Is there a difference?
A. Well, these were sent to Pete Miller as two separate documents. It may be that he combined it. He asked me to separate them. I actually started with an assessment of the pharmacovigilance system, an assessment of the risk communication.
He asked me to combine them all, the opinions, as a conclusion.
Then he said, this is too long. We want to take out this supporting document where I documented verbatim things from the FDA inspections and my comments that served as the basis for the opinion.
And this short document became the opinion and this longer document became the supporting evidence.
He may have, in the process of submitting it electronically, been forced to recombine them so that they were in this order.
Q. Just so we're -- just so the record is clear --
MR. THOMPSON: Yeah. Let's --
BY MR. DEAN:

Page 11

Q. Could you look at -- could you, yourself --
MR. THOMPSON: Yeah, could I -- let me just make a short statement, and that is, everything Dr. Frank has said is true and accurate.
Everything you said is true and accurate. That she submitted a -- the lengthy document.
We determined and we believe that for the ease of having a report and a supplement, that the thing to do would be to have it as a separate with a supplement.
But in terms of the report, the connection or disconnection is irrelevant.
And so what you have, I believe, is what Dr. Frank has as the report with, immediately following it, this lengthy discussion item by item as sort of a supplement or a supporting information.
So I think that it's tempest in a teapot. In Dr. Frank's mind, she separated them. In submission, they were submitted --
MR. DEAN: Together.
MR. THOMPSON: -- as a report with supplement, so...
THE WITNESS: Electronically on this

Page 12

there is the one combined document and then the two separate documents that were sent to Pete Miller by e-mail.
And there are copies, exact copies of this flash drive, two made, if you need to verify that.
BY MR. DEAN:
Q. So I want to get back to what you did to prepare for the deposition besides read -- read what we've marked as Exhibit 50, or the first 11 pages of Exhibit 50.
A. Well, actually, it was -- it was the great deal of this. I didn't read all the verbatim quotes. I went mostly through my comments in this document. But, no, I did not go back to the original binders yesterday.
Q. Okay.
A. I only went through the original binders to extrapolate this, because I anticipated that this would ground my statements very carefully. The -- what actually happened over the course of several years at this company is somewhat complex.
And in the course of preparing this document, I laid out a timeline of events and the observations of the inspectors.

Page 13

Because most of what I was presented was the 483s and the Establishment Inspection Reports were the paucity of what you might call primary.
MR. THOMPSON: Doctor, let me do some impermissible coaching, and that is, if I thought that it would shorten the deposition, I would let you go forward with those explanations.
But I'm afraid that we're going to get back to that --
MR. DEAN: Right.
MR. THOMPSON: -- over the course of the day.
THE WITNESS: Okay.
MR. THOMPSON: Right now, I think what he wants to know is simply what was done to prepare for this deposition, and he probably wants to know about our meeting last night and our meeting this morning.
THE WITNESS: Okay.
MR. THOMPSON: And the review of the exhibit from the deposition, and I don't recall the exhibit number, but it was the FDA document, the fact sheet.
And I think that once we say that, that will be exhaustive.

Page 14

THE WITNESS: Okay. I'm sorry.
MR. DEAN: Thank you, Mr. Thompson.
BY MR. DEAN:
Q. Go ahead.
A. Do I give him the details of the meeting last night?
Q. Well, let's just do it this way. Let me ask a question, I'll try to have a focused question, you give a focused answer.
Mr. Thompson is right, we'll get back to the substance of your opinions much later -- or later this morning. But for right now, let's just -- I'll give you a very short question, you try to give me a direct answer to the question. Okay?
A. Okay.
Q. So I take it, in the last few days, you have met with Mr. Thompson; is that correct?
A. Yes.
Q. Did you meet with any other attorneys for the plaintiffs in the last few days?
A. On the phone were Megan Carter and Pete Miller.
Q. And when did -- and was Mr. Thompson on that call?
A. Yes. He was chairing the call.

Page 15

Q. And when was that?
A. That was last evening.
Q. Was that -- within the last week, was that the first time you met with any attorney representing the plaintiffs?
A. Yes.
Q. How long did that call last?
A. Approximately two hours. It was intermittent. It was interrupted. It was scheduled to last from 5:30 to 7:30.
I was down in the lobby at 6:30 expecting Mr. Miller to meet me, and at quarter of 6:00 I called him on his phone and he had expected me to call him when I arrived. So we started late and I believe we went about 15 minutes late.
Q. What subjects did you discuss?
A. I discussed some general opinions that I had about the situation and some specific issues that came from the evidence here. They presented me with the issues that had come up in the depositions.
And we talked about how I would stick to the scope of my engagement, how I would respond if the questioning started to go outside of the scope of my engagement.
They made me aware of some additional

Page 16

documents that I was not sent, that -- there was suggestion that I review them last night or sometime in the future to further expand the analysis.
There was discussion of some general FDA press releases on generic drugs and their implications that they may be presented to me today.
And there was -- there was just some general coaching in how to give appropriate opinions. And I believe they were very, very careful to stay within bounds with coaching the witness.
My only other presentations such as this are before FDA advisory committees, which are largely data driven. They were internal, closed-door presentations. And they were very carefully reviewed up front. So --
Q. Excuse me. I missed that. They were very carefully what --
A. Reviewed up front with FDA supervisors.
Q. Okay.
A. So this is the first time I've sat at deposition. I will make a statement that I've been approached about doing this work previously, maybe eight years ago. People recommended --
MR. THOMPSON: Dr. Frank, let me ask you to be responsive to Mr. Dean.

Page 17

THE WITNESS: Okay.
MR. THOMPSON: I think he has now exhausted the -- maybe he hasn't exhausted, but we're on the preparation for this deposition.
THE WITNESS: Okay.
BY MR. DEAN:
Q. All right. Thank you for that answer, which I think was responsive, but I want to go back and ask you some follow-ups on specific things that you said in that answer.
You said, first of all, that they -- "they" being the lawyers -- presented you with issues that had come up in the depositions, by that I mean -- I'm assuming you meant depositions that have occurred in the last few days?
A. Yes.
Q. What issues did they present you with?
A. The one that really struck me was the fact that the -- there was a repeated line of questioning about specific information on Digitek.
And I responded to them that if you were to look at the volumes that I reviewed several weeks ago to write this document, you will see in my notes in the margin, Digitek question, Digitek question.
Because there's not a lot of specific

Page 18

information given on the systems that allow specific analysis of the subset of data on Digitek.
And so I understood why your line of questioning went in that direction, and we prepared me to answer. And I think I can -- I've produced a document that can -- is an accurate basis for any answer to that.
Q. I don't -- I want to follow up. You said they presented you with the issue that there was not much specific information on Digitek.
Could you be more specific about what the issue was they were talking to you about?
A. They didn't state that there was no specific issue on Digitek. They said that your line of questioning repeatedly was to ask the witnesses do you have anything specific on Digitek.
My extrapolation was my reaction to what I was given is that I was unable to subset out information on the systems specifically for Digitek.
So when the FDA looks at noncompliance with 15-day reporting, they have a sampling that includes Digitek cases and non-Digitek cases.
I don't know how that extrapolates. Nobody presented me with data from the database that shows X Digitek cases over X years, the adverse event

Page 19

codes.
So I can't say that the analysis of the databases or the systems was specific for Digitek. It was analysis of the Actavis systems that handled all of the products. Nothing was specific to Digitek.
MR. THOMPSON: You know, let me just interrupt here. Certainly you have a right to ask questions and certainly Dr. Frank has shown that she's going to be meticulously responsive.
But if we're going to go through all this again and you're going to ask the question that we told her that you were probably going to ask, I'm just not -- I just hate to sit through it twice.
BY MR. DEAN:
Q. What other issues did they present you with besides the one you just spoke to us about?
A. I'm having trouble recalling specifically. We talked a lot about my staying within the scope of my engagement because --
Q. I don't need to go there. I understand that.
I just want to know, I'm interested in what issues they flagged for you last night. You've told me about one issue.
Are there any others they flagged for

Page 20

you?
A. I need to -- I wrote notes, but I don't think I have written them all down, and I don't --
Q. Did you make notes at that meeting, ma'am?
A. Nothing -- only my to-do list for last night.
MR. KAPLAN: Can we get a copy of that?
MR. DEAN: Well, let me look at it first. I'm not sure we want it.
MR. THOMPSON: Why don't you look at it before you say that.
BY MR. DEAN:
Q. For Mr. Kaplan's benefit, could you just read what's on here so -- I don't think we're going to need a copy of that.
A. It says, Two flash drives, check e-mail. And I don't know -- I don't know what the other one says.
What I wanted to make sure is that I had all of the required evidence that you wanted for the deposition.
Q. Now, let's -- thank you.
Now, I want to make sure you've answered my question, though. I just want a listing of the

Page 21

issues they presented to you. You've given me one issue.
Are there any other issues?
A. They talked to me about how to respond to questions that had multiple questions in one question, to ask for it to be subdivided. They --
Q. Excuse me. I'm not interested in their instructions about how to respond to questions.
What I'm interested in are simply this. Are there substantive issues at the beginning of the meeting that they flagged for you as issues that might come up in the deposition? That's all I want to know.
A. At the moment, I can't remember any more.
Q. Okay. Thank you.
Now --
A. I think -- I'm sorry I'm so nervous, but I'm -- actually, I can't remember the specifics.
Q. You'll get more -- I know at the beginning this is -- you're going to be nervous. You'll get comfortable.
And if you think of those issues later, if they come back to you, we'll give you an opportunity.
A. Yes.

Page 22

MR. THOMPSON: I hate to -- I hate to interrupt again, but I do believe Dr. Frank did mention that we read to her the FDA Generic Drug Advisory.
MR. DEAN: I've got the list here.
MR. THOMPSON: Okay.
MR. DEAN: I'm getting there.
MR. THOMPSON: Okay.
BY MR. DEAN:
Q. The next thing you mentioned when you were giving me the list of what happened last night was that they gave you additional documents that had not been sent to you.
What documents did they give to you that had not been sent?
A. They were unable to access the server. The only way to obtain some of the documents was through the Citrix portal on his laptop, and that was not functioning. They were unable to download the documents and send them to me by e-mail.
Your line of questioning along specific issues for Digitek brought up issues that were already of concern to me.
So a lot of what happened last night was, I expressed my concerns and they responded to

Page 23

prepare me to address my concerns this morning.
And in coaching me to stay within the scope of my work, there were a number of documents that were not sent to me, but were sent to the other witnesses, the cardiologist who looked at the medical issues.
Even though I'm a medical doctor, I was not sent a lot of these.
So we talked about that. We talked about my concerns with the process of discovery in this case.
Q. Now, let me just stop you. You've gone beyond my question. I'm going to give you a chance to tell me whatever you want to tell me, but I'd like to do it in a question-and-answer fashion.
Did you look at any additional documents last night or were you foiled by technology from being able to look at additional documents?
A. We were foiled by technology, except for one document.
Q. And what is that, ma'am?
A. Which is a generic press release by the FDA talking about the generics industry where they read to me specific points and warned me that it may be presented to me today.

Page 24

Q. Okay. And did you look at any additional documents this morning?
A. I read these this morning.
Q. Read what this morning?
Oh, no. I meant -- I meant additional -- additional evidentiary documents, exhibits.
A. No.
Q. Okay. So the only additional document that you looked at in the last two days was that -- what you referred to as a generic press release; is that correct?
A. Yes. Now --
Q. Is that correct?
A. Yes. You --
Q. You've answered. Okay? It was a very simple question.
Let's -- let me go on and frame another one for you.
A. Okay.
Q. I believe in your original answer to me you mentioned that you discussed some FDA statements.
Was that just the generic statement we just spoke about?
A. Yes.
Q. Yes?

Page 25

A. I didn't see anything else in writing.
Q. Now, about three minutes ago you said that this morning you expressed your concerns about some issues.
A. Well, last night and this morning.
Q. Okay. And what concerns did you express about issues?
A. Well, I wanted to be certain that I didn't violate any of my existing confidentiality agreements.
A lot of the background I draw from has to do with -- has to do with issues that I addressed in pharma companies or where I had been provided information from my FDA mentors about drug withdrawals.
I know a lot about the investigations that went on in some of these and they coached me how to comment on this evidence without bringing in evidence from other cases that would not be appropriate for this deposition.
I expressed my other concern that when I was given these documents, I went through them, I then made a list of documents that I would like to have seen to completely analyze what happened in the company, and I presented to Pete Miller, and they were

Page 26

concerned that the process of discovery was complete and those documents were not available.

I did not go back and do the subsequent gap analysis when they sent me the second round of documents.

But in this document I prepared for myself for this morning, I tried to clearly lay out what I -- what was provided to me very accurately, and things that were not provided to me, like any of the MHRA inspections or the responses.

So my view inside Actavis, from 1992, from the first consent decree, to now, is mostly through the eyes of the FDA inspectors and their observations.

And my opinions can only be based on what I actually saw or read. These are secondary sources.

I haven't seen the primary sources. I haven't seen any individual MedWatch forms. I haven't seen any PSURs.

I have not seen the company internal document that was provided to Dr. Leikin at the time of his Health Hazard Assessment. I have not seen the Quality System Improvement Plan. I have not seen any CAPAs, any CAPA trackers.

Page 27

MR. KAPLAN: Any what?

THE WITNESS: CAPA trackers. When companies have CAPAs, they usually track their compliance with the CAPAs with some sort of a tool. Some are more robust than others. Some can be as simple as an Excel spreadsheet.

But if they have an inspection and they're anticipating a repeat two-year inspection, they're documenting their remediation program on the original inspection and what are their vulnerabilities for the repeat inspection.

If they're working with a consulting firm on business processes, they usually provide this information to the consulting firm for the business analysts and the modelers to use in assisting them in building more robust business processes and improving their compliance.

MR. THOMPSON: Let me -- here again, let me -- this is not even an objection, is if I thought that this was actually covering this information for the whole day, I would allow Dr. -- I would say go, continue, Dr. Frank.

She's clearly trying her best to give full and responsive answers, but I'm concerned that we're going to just repeat this same material and

Page 28

we're going to hear it twice.

So it's my hope that we can -- it's my hope that she'll tell you that we told her to tell the truth at some point, but even if she doesn't --

MR. DEAN: She's left that out so far, Fred.

MR. THOMPSON: Yeah. I think we've -- anyway...

BY MR. DEAN:

Q. For Mr. Thompson's sake, did Mr. Thompson tell you to tell the truth today?

A. Yes.

Q. Good.

A. Do you think I'm not telling the truth?

MR. THOMPSON: No. That's a lawyer joke between the two of us. I apologize.

THE WITNESS: I have a concern that the complexity of this -- I've been involved with companies that have had implosions like this, and in trying to correct it inside the company, the exhaustion that occurs in trying to sort out what happened and what needs to be corrected, how to correct it and document the correction can be prohibitive.

And in trying to sort out what really

Page 29

happened here very, very accurately, I don't want to come in and make general statements that sound like opinions.

There's -- there's a lot of evidence here as to what happened, what was not reported, what the inspectors found, what the companies promised to do, what they did do in the remediation.

But there's white space that I have not seen. It's not -- it may or may not be in the process of discovery. It may have been that in limiting the scope of my opinion it was not provided to me, it was provided to someone else.

BY MR. DEAN:

Q. Okay. Let me hand you what I have marked as Exhibit 90.

MR. DEAN: Fred. Harvey.

BY MR. DEAN:

Q. Exhibit 90 is a Notice for this deposition asking you to bring certain documents with you.

Have you seen this before?

A. Yes. I went over this with them last night.

Q. Okay. Let's go through it.

Item number one, we already have your

Page 30

curriculum vitae.
Item number two was correspondence between you and any attorney acting on behalf of the plaintiffs in the Digitek litigation.
Did you bring that with you?
A. I have everything. I asked specifically twice whether I was to print e-mails. I was told no. I do not have any e-mails corresponding to the case.
I asked them not to send any documents by e-mail. Everything was sent by FedEx either in paper or electronic format.
Q. And did you bring items responsive to number two with you today?
A. Yes.
Q. And could I see that, please.
A. I believe that I did print some SOPs, but I did not make comments on them. So what I know about document retention, I didn't alter the paper copy, and there is an electronic copy. It's equivalent.
So I don't think I have all of the SOPs that I printed, but I have the electronic equivalents and there were no marks made on these.
Q. Dr. Frank, you have given me four notebooks, some loose pages of paper and two CDs;

Page 31

correct?
A. Yes.
Q. What is on the CDs?
A. As many of the documents in these notebooks and that stack as were available electronically.
Q. Okay. So these, the CDs, would not comprise everything that's in hard copy here?
A. No. And I went back and asked, and I don't think all of them were available electronically. There were some that were to be delivered.
That -- see that sheet there? That is the listing of at least one of the CDs. And the checks, I don't recall having received electronically the two documents there.
Q. Well, if I was interested -- I'm not interested in hauling all this paper with me, but -- or having it marked as exhibits if I can avoid it.
There's a document here that says Documents sent to Karen Frank; correct?
A. Yes.
Q. Does it -- does this summarize some of these notebooks?
A. Yes. Now, what I did not do --

Page 32

Q. Excuse me. Which notebooks would it summarize, Dr. Frank?
A. I think the first two that were sent to me.
Q. So -- and which would those be?
A. Okay. That would be that one there (indicating).
Q. Okay.
A. And I specifically did not take time to categorize this. I called them and said, I don't have all the documents electronically for which I want to write this document. But I did not take the time to verify those disks against the binders.
Q. Did you --
A. And there could be variation, is what I'm saying.
Q. I want to move through this as quickly as we can.
But what I'm interested in is what you were -- what you were provided and then what you asked for, is -- in follow-up, is all of that here in front of us now?
A. Yes.
Q. Is there anything that's responsive -- strike that.

Page 33

Is there anything else you brought with you today other than what we have on the table?
A. No. The directions to the hotel last night and my Notice.
Q. Those I don't need.
A. And this you have in electronic format, all of this.
MR. THOMPSON: Let me interrupt. She brought these two thumb drives, which are two copies of the same thing. Maybe she needs to summarize what's on the thumb drives.
MR. DEAN: Yes. Thank you, Fred.
BY MR. DEAN:
Q. Could you do that, please?
A. When I started the review, the consulting firm that I worked for had me talk to somebody else who was doing expert witness work. And he said that he did individual reports of every document he reviewed. So I started that.
But you will not find a whole lot of comments expressed in those documents because I held back very carefully. So there weren't frivolous comments made. Become -- what I did was --
Q. All I want to know is, what's on the thumb drives?

Page 34

A. Those draft documents are here.
Then what I did is, I became concerned about the complexity of what had happened and the amount of white space, and I started putting my own document together that is as close as I can track to verbatim quotes from the FDA inspections and the documents that I received.
And after I put that together, I started going back and making substantive comments on that. And from the substantive comments, I drew the conclusions.
It was a step-wise process that involved stopping the individual reports on the individual documents.
That became out of scope, unauthorized work, and it was rolled into one review document with substantive comments and the conclusion.
Q. Let's go back to Exhibit 90, please.
MR. THOMPSON: I think what she was saying was that the various draft iterations of the final document --
THE WITNESS: Right.
MR. THOMPSON: -- are contained on the thumb drive.
Is that right?

Page 35

THE WITNESS: Yes.
MR. THOMPSON: Okay.
THE WITNESS: This whole process, including the truncated short reports.
MR. THOMPSON: Okay.
THE WITNESS: Which you're welcome to review, which should not have -- they will have comments, they won't be substantive. They were very, very lightweight comments.
The heavy comments were, for the most part, restricted to this document and very carefully tracked to the verbatim evidence.
MR. THOMPSON: Okay.
BY MR. DEAN:
Q. What I'm -- thank you.
What I'm trying to get at now -- and I appreciate your answer. What I'm trying to get at now is the documents that are called for in the -- in the Notice, which is Exhibit Number 90.
And so all the correspondence and communications you would have would be in what we have in front of us right now; correct?
Would be somewhere in here; correct?
A. Yeah.
Q. All right. Where, in terms of

Page 36

correspondence and communication, were there -- are there letters in here?
A. No.
Q. So did you -- did you ever exchange letters with one of the plaintiffs' lawyers?
A. I received cover letters for each of these binders that I did not retain.
Q. So the cover letter would have -- it would have just had a listing of what was in the -- in the materials; is that right?
A. It didn't even have a listing. It looked like their generic cover letter.
Q. Enclosed please find?
A. Yeah.
Q. Okay. All right.
A. And the other thing that may be missing is, when I -- when they -- they coached me through the preparation of a nice document for you. Not for a client that's in trouble that needs to remediate.
So there may be a few phone calls where I had a pad in my hand and I scribbled notes to myself. They were translated into this. Those notes probably --
Q. Translated into what, ma'am?
A. The documents that they were part of.

Page 37

Q. Would they -- if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?
A. Some of them are.
Q. Okay.
A. There may be -- there may be stray notes that were lost.
Q. Would it be -- would it be fair for me to assume that if there are such notes, they would be in this stack of paper right here?
A. Yes.
Q. Could you -- could you --
A. The -- the --
Q. Well, hang on. I can make it even easier.
Because Plaintiff's Exhibit 91 is in here; correct?
A. Yes.
Q. So --
A. I can tell you what I think is missing.
Q. Well, let's stay on -- let's stay on task here.
A. Okay.
Q. We're on number two. Is there -- in what you've brought with you today, is there any

Page 38

correspondence between you and the plaintiffs' lawyers?
A. Nothing of substance.
Q. Is there anything? In what we have here, is there any correspondence?
A. No. They're only documents. The letters were all these generic cover letters.
Q. All right. Fine.
Then number three, it says, all other documents prepared by attorneys for the plaintiff and sent to the witness.
Would they all be in front of us here?
A. Can you repeat the question?
Q. Yes. I'm on number three, Dr. Frank.
We asked you to bring all other documents prepared by attorneys for the plaintiffs and sent to the witness.
Would they all be in front of us?
A. Yes.
Q. Okay. It says, all documents including documents and deposition transcripts which you have received from any source.
Now, you didn't -- are the -- if I remember right, you reviewed the deposition of Sarita Thapar and Misbah Sherwani; correct?

Page 39

A. Yes. They're in these binders.
Q. Okay. Do you --
A. May I ask a question?
Q. Do you know -- in a minute.
Do you know which binder they're in, Dr. Frank?
A. Right here and here (indicating).
Q. Well, we're making progress, Dr. Frank.
One of these notebooks, which says 1 of 1 --
A. Yeah.
Q. -- contains the deposition of Misbah Sherwani and all of her exhibits to her deposition; correct?
A. Uh-huh.
Q. Is that right? Yes?
A. Yes.
Q. So we're going to get that notebook off the table. I'll put it back over with your material later. I just don't want to unhook from my --
A. Yes.
Q. And then another notebook, which says 1 of 1, says Deposition of Sarita Thapar; correct?
A. Yes.
Q. And contained within it is her

Page 40

deposition and the exhibits to her deposition; correct?
A. Yes.
Q. So we're going to get that one off the table.
A. Now, that had --
Q. Now, you said "that," we have two notebooks. Let me -- which one did you want to refer to, Dr. Frank?
A. The one where I removed the cover sheet, which I should not have done. I apologize.
Q. So this is the smaller notebook you were talking about?
A. It's the later. The one where I removed the cover was the first. There were cover sheets, similar cover sheets.
Q. I have two notebooks. They each do have a Table of Contents; correct?
A. Yes. Yes.
Q. And did these both come at the same time or did they come at different times?
A. Came at different times.
Q. Which one came first, Dr. Frank?
A. The one where I removed the cover.
Q. Is that the larger one, the larger

Page 41

notebook?
And this notebook --
MR. KAPLAN: You have to say yes or no.
THE WITNESS: Yes.
BY MR. DEAN:
Q. It may not be relevant for our purposes later on, but this notebook has no markings on the outside. But it does have a Table of Contents on the inside, which we will -- which we will mark as an exhibit.
MR. DEAN: And can you just give me an arbitrary exhibit number? Should we do something, start at -- call it 250, do you think?
MS. TAKLA: Sure.
MR. DEAN: Why don't we -- we will mark this later as Exhibit 250 so we don't have to go off camera right now.
Make a note of that, please.
BY MR. DEAN:
Q. This notebook says, Digitek Expert Table of Contents. It has 18 items; correct?
A. Yes.
Q. Okay. And when -- and this was the first information you received; is that correct?
A. Yes.

Page 42

Q. Do you recall approximately when you received this notebook?
A. Sometime in the beginning of May.
Q. And then what is the second, smaller notebook?
A. That contains some of the additional documents that I requested.
Q. So this has a document -- this has a Table of Contents that has 11 items; correct?
A. May I say something?
Q. Of course.
A. I'm actually concerned that there's one more binder. But I moved these to the side of the office and stacked them specifically several weeks ago.
There's a problem in that I cleaned out my closet with all of my old binders from my fellowship at the FDA, and I can't imagine that I mixed these binders in the stack with my old binders at the FDA, but I need to make you aware of that.
Because I recall that I got more binders, and --
Q. I'm sorry, you said you recall you got more binders?
I want to make sure I heard you

Page 43

correctly. Did you say more?
A. I'm trying to remember whether there was a fifth binder and I'm a little bit embarrassed.
Q. Well --
MR. THOMPSON: Let me say --
BY MR. DEAN:
Q. We'll come -- let me -- let me finish the questioning on this and we'll come back to that. Okay.
So this one that says -- it has 11 items, and we're going to mark this as Number 251, the Table of Contents. You said that it represents documents that you requested; is that correct?
A. Yes.
Q. Okay. And when did you make the -- when did you make that request?
A. At a lunch meeting with Pete Miller, and I can check the date in my date book. Do you need the exact date?
Q. Well, I would like to get an approximate -- yes, I would like -- yes, I would like to know when you made the request. Yes.
If you've got a note on that, rather than guesstimating, that would be good.
A. It was Wednesday, June 2nd. I met Pete

Page 44

Miller and Megan Carter at the Philadelphia Airport at either 12 o'clock or 1:00 p.m.
Q. Doesn't matter what time you met.
So that's the day you requested these documents; is that right?
A. Yes.
Q. Now, when you requested, did you -- did you hand them a list? Did you give them -- did you send them an e-mail?
How did you convey the information to them?
A. I had made a list for myself, and I believe that list is in here.
Q. Okay. And then how shortly after that meeting did you receive the smaller notebook?
A. It took a while. I think they were sent by FedEx ground, rather than FedEx overnight, because I called them twice concerned that there was a delay.
MR. DEAN: Actually, you have exhibit stickers I see, don't you?
Why don't you go ahead and we'll -- is it all right if I mark the original with the exhibit sticker?
MR. THOMPSON: That's fine with me. I don't know the terms with this law firm. Can we make

Page 45

a copy here?
MR. DEAN: Yes. We can get copies. I just want to get it marked so that --
MR. THOMPSON: Yes, that would be -- that's actually a good idea.
MR. DEAN: Yes. If you'll give me an exhibit sticker, I'll go ahead and mark this so we don't get confused later on.
(Exhibits D-250 and D-251 were marked for identification.)
BY MR. DEAN:
Q. And, Dr. Frank, we'll get copies for everyone later. But the larger notebook, the Table of Contents, I've marked as Exhibit 250.
Do you see that?
A. Yeah.
Q. And that was the one you received initially; correct?
A. Yes, in its entirety.
Q. And then Exhibit 251 is the notebook you received after your meeting with Mr. Miller and Ms. Johnson; right?
A. Yeah.
Q. And then you said, I think you were just telling me, that somewhere in this other stack of

Page 46

papers would be a list where you request -- you made the request for follow-up documents; is that right?
Could you look and see if you could find that for me.
A. These were the documents where I started listing what I did and did not have to review and tried to define what you might call the white space in the dossiers. They're not --
Q. First of all, let me pause here. Let's stay on the question.
Is there a document either which you handed to me or that you still have with you that represents a listing of the documents that are in the smaller notebook?
A. No. I did not request those specifically. I talked to them about my concerns about what I called the white space or the absent documents in what I was sent, and they made the decision what additional documents to send me.
Q. Okay. So then what is represented in the smaller notebook that's got Exhibit Number, on the Table of Contents, 251, is a selection of documents that Mr. Miller and Ms. Johnson sent to you after hearing general concerns about white space; correct?
A. Yes. But I --

Page 47

Q. You -- just so we're clear, you did not give them this list?
They made this selection based upon what you -- some concerns you had expressed; is that fair?
A. Yes.
Q. Okay.
A. About those lists that I started to --
Q. Hang on. I'll get to these. Okay?
A. Okay.
Q. We're just going to try to -- I'll try to ask a focused question, you try and give me an answer and stop, and then I'll ask you another question. Okay?
A. Okay.
Q. All right. Now, you have handed to me -- from the loose documents, you've handed to me looks like three different documents; is that correct?
A. Uh-huh.
Q. Yes?
A. These were prepared --
Q. Hold on.
MR. DEAN: Let me mark these so we're clear so we don't get --
(Exhibits D-252 through D-254 were marked for identification.)

Page 48

BY MR. DEAN:
Q. All right. Let me hand you first what I marked as Number 252.
Could you tell us what that is, please.
A.
These were notes to myself --
Q. Please keep your voice up, too.
A. These were notes to myself as I tried to define what was sent to me as far as the sequential FDA Establishment Inspection Reports, warning letters, the company responses and CAPAs, so that I was defining what I was going to be basing my opinions on.
Q. Is that kind of a summary of the -- not of every document, but the kinds of material that you had received?
A. Well, I got frustrated and concerned that I was being asked to render an opinion on what happened in a company, and I had only selected documents over the period.
So I don't have the -- a lot of company responses and CAPAs. I don't know many things about the adequacy of their remediation plans.
And then I actually -- this is a preliminary list. I didn't expect to give it to you. But I then started to sort out when I did this in my

Page 49

comment document, the company's responses.
How many letters went back and forth to -- between the health authorities and the company and what were the comments, the substantive issues in those.
I did not go from here to here and say, oh, I found this warning letter. There could be inaccuracies in this. This was my preliminary list.
Q. Could I just see that briefly, please.
A. (Witness complies.)
Q. Could you tell me briefly what 253 is.
A. This -- these are notes that I took in writing the very early individual reports. And there are a lot of very close notes or verbatim transcripts of the documents as I went through them in excruciating detail.
And then what I wanted -- what I should have done is asked for them up front electronically. But this became the basis of this report here.
Q. So Exhibit 253 is a document you used when you were writing what we marked as Exhibit 50; correct?
A. This could be considered an early draft of Exhibit 50.
Q. Okay. Very good. Thank you.

Page 50

And for the record, what is 254?
A. More notes to myself.
Q. Do you remember what -- what do they generally represent?
A. I believe these are my notes from the meeting with Mr. Miller and Ms. Carter on June 2nd.
Q. Could you read for me this particular entry, it starts out documents, I think. And you write pretty well, but I'm just having trouble reading that.
A. Well, this is not that good. I wish that -- if I had known that these were going to be given to you, I would have notated them much more carefully.
Q. Just try to, as best you can, read that one sentence for me.
A. It says, preponderance of the evidence, civil.
Q. Excuse me.
A. Right above that?
Q. Yes. That one right there.
A. Document for withholding.
Q. Do you know what thought you were trying to capture there? And if you don't, just tell me.
A. I think it's the time that I decided --

Page 51

this may have been to myself -- that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.
Because of this type of situation and the complexity of what happened in the company, the intermittent evidence that was presented, the fact that there's things that I would have liked to have seen that we couldn't obtain, that I wanted to carefully track that for this very situation, so I could present to you what I had, what I did not have, and track the opinions very, very closely to what I was able to see.
Q. Did you ever submit to the plaintiffs a listing of documents you thought you were missing that you specifically wanted them to provide to you?
A. I gave Pete Miller some notes from the meeting as I was talking in generalities. I don't remember that was -- if that was on the back of the list. I don't -- I did not type up a specific list. I believe I showed him these.
Q. These being what? Which exhibit number?
A. These preliminary assessments of the white space.
Q. Being Number 252?

Page 52

A. Yes.
Q. Okay. Let me go back to my question because my question I think was focused. I think you've come close to answering it.
But did you give a specific list of documents to Mr. Miller to fill -- which, in your mind, would fill out what you are calling the white space that you wanted to be provided?
A. I think I had the list in front of me and I read down it. I may have translated a few of those to another paper, but he responded to my going down the list what was and was not available at that point in discovery.
The fact that discovery was complete and then there was discussion of there may be another round of discovery and the possibility of obtaining those documents.
But I did not type up a list or write up a specific list that I handed to him. And I can't recall the specifics of the exchange. A lot of this was my asking questions of them.
How do I prepare these documents for expert witness and can I get any of these?
I would have these if I was an FDA medical officer. I would have some of this

Page 53

information if I was inside the company and helping with the remediation.
Can you get this for me now so my opinion can be based on a broader and more complete compilation of the evidence?
Q. Can we agree, then, that you never gave Mr. Miller or any plaintiff's lawyer a specific list of documents that you wanted to look at?
Can we agree on that?
A. Yes. And next time I will very carefully.
MR. THOMPSON: Dick, I can put an exhibit right here. That's the -- you got that; right?
MR. DEAN: Right.
MR. THOMPSON: Okay.
(Exhibit D-255 was marked for identification.)
BY MR. DEAN:
Q. I'm handing you what I've marked as Defendant Exhibit 255, which is entitled Documents sent to Karen Frank, and it has 29 items listed on it.
And I see that 250 and 251, one has 18 and one has 11, so that would be 29.
Is life so good for Mr. Thompson and me

Page 54

that Exhibit 255 is simply a compilation of the Table of Contents of these other two notebooks?
A. I believe so. I called their admins to ask about these, and I think about this one.
Q. First of all, you --
A. Yes.
Q. I want to give you the opportunity, but do you -- if you need to look at it, but is 255 simply a compilation of what we have on the Table of Contents on 250 and 251?
A. I believe so, but I specifically did not check. I did not bill them for time verifying this against either of those binders or against the electronic.
Q. When was 250 -- did you prepare 255 or did someone else?
A. Someone else did.
Q. Do you know who did?
A. One of the admins or paralegals at the Miller firm.
Q. Okay. Why don't you let me have that one back.
A. (Witness complies.)
Q. Now, you just pointed out that there's some handwriting in red ink on here. Is that your

Page 55

handwriting?
A. No. That's from the admins at the firm.
Q. Okay.
(Exhibit D-256 was marked for identification.)
BY MR. DEAN:
Q. What is 256?
A. That is my notes from a discussion with Smart Consulting about the way another expert consultant approached review of the cases.
Q. And that consultant would be Mr. Farley?
A. Yes.
Q. When -- is this in your handwriting?
A. Yes.
Q. And who did you speak to?
A. On the telecon were Denise Smart, Nigel Smart, and Jim Farley.
Q. And what was the occasion for the four of you to speak to each other?
A. Remember earlier I said that I had been approached about doing this kind of work in the past?
Q. Yes.
A. Well, I had declined it. And Smart Consulting approached me about doing this expert witness work.

Page 56

I was a little loathed to move in to litigation. And this was the first time I had done any expert witness work. I was not certain how to prepare the documents, how to format the documents.
I prepared FDA reviews, I prepared things to go to the health authorities, but I was asking him questions about being an expert witness and trying to determine if I was going to tactfully decline this engagement and simply not undertake expert witness work.
And I had discussions with Mr. Miller and with Megan Carter in sorting out, you know, how to proceed with the work. So there was coaching and advice as I began to develop a way to develop these documents.
I asked them for copies of Jim Farley's documents so I could format them appropriately. And they did not want to do that because they were in draft.
So they gave me indications of how they wanted the documents formatted.
So what you're seeing is indication of somebody who had not previously done expert witness work taking on assignment and being rather transparent with the consulting firm and the attorneys as to my

Page 57

present state of experience with this and getting advice on how to proceed.
Q. Did Smart -- are you working through Smart Consulting in this litigation?
A. Yes.
Q. Did they recruit you for this assignment?
A. Yes.
Q. Had they already recruited Mr. Farley?
A. Yes.
Q. Was Smart Consulting the first company that approached you about taking on this assignment?
A. Yes.
Q. And when was that?
A. I don't recall the date, but I do have a signed copy of the Consulting Agreement.
Q. Is that in the documents we have here?
A. Yes. I scanned it with my date of signature.
Q. Where is it? Is it in one of --
A. You have a scanned electronic copy of this document. That was the one that was faxed to Smart Consulting.
You need that copy?
MR. DEAN: Yes.

Page 58

MR. THOMPSON: Well, that's your original?
THE WITNESS: It's my original.
MR. DEAN: Well, you're going to get it back, just with an exhibit sticker on it. Is that okay?
THE WITNESS: Yes. Whatever you need.
(Exhibit D-257 was marked for identification.)
BY MR. DEAN:
Q. So 257 is a copy of that agreement; correct?
A. Yes.
Q. Had you ever -- before this agreement, had you ever done anything with Smart Consulting?
A. I provided them with some business processes for a proposal in 2009 on product complaints.
I believe I was recruited to be on a proposal for another consulting assignment, and for confidentiality, I don't think I can tell you what the client was.
But I did not provide any information to Smart. They had two spots that I could possibly fit in and there was a phone conversation as to how I

Page 59

would fit best into that engagement.
And then I did some work on a REMS proposal for them back probably in March of 2010 where we did not win the engagement.
And it was on the basis of those interactions that they approached me about being an expert witness on this case.
And Nigel Smart was very adamant that based on his interaction with me that he thought that my background was completely adequate to make substantive comment on what would be sent to me and that it was an appropriate assignment.
Q. Is Nigel Smart an attorney?
A. No. He's a Ph.D. who has done this work.
(Exhibit D-258 was marked for identification.)
BY MR. DEAN:
Q. What's Defense Exhibit 258?
A. That was part of the background that was submitted in the first binder.
Q. So this is a document prepared by one of the plaintiffs' attorneys and would have been contained within the notebook where we have the Exhibit Number 250 is the Table of Contents?

Page 60

A. Yes.
Q. Is there some reason why it was removed from the notebook?
A. It wasn't deliberate. What I have are the loose documents in a stack and the notebooks. But there -- no, there was no -- I did not cite that or the injunction or the consent decrees in my reports.
It was reviewed initially, possibly reviewed twice, but I did not use it as evidence.
Q. Are these separate pages or are these one document?
A. They're separate.
(Exhibits D-259 and D-260 were marked for identification.)
BY MR. DEAN:
Q. What is Defendant 259?
A. I was trying to sort out what was the business process in the company for evaluation of out of spec results, product complaints.
There was no evidence provided to me that the work that I did in industry of doing routine Health Hazard Assessments was being done, and I wasn't certain whether it was just that I didn't receive the documents.
But when I've done work for clients

Page 61

who've been inside companies and there is a manufacturing deviation, particularly if it's released in the market, I would usually get a copy of an investigation where if they had a sample of the product, they would bring it back in-house and do analytics.
If they needed to, they would check it for bacteriology. They would then go back and do an investigation in the plant, you know, a real root cause analysis.
I would be provided with an investigation report that would define the batches at risk for a single drug or even if multiple drugs had been through that piece of malfunctioning equipment.
Q. This would be a product complaint you're talking about?
A. Yes, in another company.
Q. Right.
And just so I'm clear, you're talking about in other companies you work for where there was a product complaint, there would be a system in place where a complaint form would be generated and processed through the system; is that correct?
A. Yes.
Q. Okay.

Page 62

A. And --
Q. And did you -- did you make any inquiry in this case as to whether there were product complaint forms that you could look at and see how they were processed?
Did you ask the plaintiffs' lawyers for that type of information?
A. Yes, I did. I commented on June 2nd on the absence of this information, and --
Q. Let me just ask you, did the plaintiffs' lawyers ever provide to you any product complaints on Digitek?
A. Yes. But I believe they were after the recall. What I did receive was the investigation report of the double-thick tablet of Digitek. The complaint registered by a pharmacist in Bellingham, Washington, in July of 2004.
Q. I'll get back to that. I don't want to -- heeding Mr. Thompson's admonition, I don't want to repeat myself.
But let me just ask you: As I understood it, you asked for product complaints on Digitek before the recall, also, didn't you?
A. They were not on my list. I didn't say product complaints that I can recall specifically.

Page 63

Q. So you did not -- so just so I'm clear, you did not ask the plaintiffs' lawyers to provide product complaints on Digitek prior to the recall; is that correct?
A. I believe they were volunteered. What I was looking for was investigation reports of product complaints and realtime Health Hazard Assessments, which would have been generated from those product complaint reports.
Q. Did you ask for product complaints on Digitek prior to the recall? Yes or no?
A. I would have to say no, unless you would consider it implied in asking for evidence that would confirm that those business processes were in place and in use during this period.
Q. Okay. So -- but you didn't specifically ask for them; correct?
A. No.
Q. Okay. Fine.
A. May I?
Q. You can go ahead and say whatever you'd like to say.
A. It may be a result of my naivete, and I assumed that these were manufacturing issues and they were going to another consultant whose expertise was

Page 64

in the investigation of product complaints, which I've never done.
I received the results to write the Health Hazard Assessments. So my absence of asking for them may have been my assumption of where they were to be directed.
MR. DEAN: Okay. Let's take a break.
Our tape needs to be changed. We'll get some copies of exhibits and we can all stand up and walk around a little bit.
Let's go off the record.
THE WITNESS: Okay.
VIDEO OPERATOR: Going off the video record.
This is the end of Tape 1.
The time is 10:27 a.m.
(A recess was taken from 10:27 a.m. to 10:43 a.m.)
VIDEO OPERATOR: We're now back on the video record.
This is the start of Tape 2.
The time is 10:43 a.m.
BY MR. DEAN:
Q. Dr. Frank, I think we just have a couple more documents to mark and have you identify and then

Page 65

we'll get into the substance of this.
I don't think I've asked you what Number 260 is.
A. This is more notes.
Q. And do you know what day you took those notes, what the occasion was for taking those notes?
A. I'm trying to remember whether I made them before or after the meeting with Pete Miller on the 2nd.
As I said, I was coached somewhat into how to leverage my FDA experience, my industry experience, to produce work products for attorneys as an expert witness.
And I actually started this project with my, what I'll say, my modus operandi as an FDA medical officer.
And then I started to tease out what I could about what was going on inside these companies, what business processes were in place and in use.
And I brought some of these notes to the meeting with Mr. Miller and Ms. Carter, and there were some that I made.
And I started to explain to them my concerns that I couldn't piece together things from the FDA inspections. And then they provided me more

Page 66

documents where the FDA clearly documented things.
And that's the basis of this large document, it's finding the answers to these questions or any information that elucidated how -- are these business processes in place. So these are my notes to myself.
Q. Taken at a meeting with Mr. Miller; is that right?
A. Or sketched at a meeting with Mr. Miller to say these are things that typically occur in a company and what -- while I'm looking at inspection reports that are samplings of compliance with SOPs, I don't have any SOPs or work flows and I'm trying to piece together what was in place and in use from the FDA reports and the warning letters.
And that's when I asked for more information to start to give myself a clearer picture.
Q. Okay. You also brought with you a copy of Plaintiff's Exhibit 91, which is a 2008 IDR.
You also brought a -- in your papers was a February 28, 2006 letter from Amide to the FDA; correct?
A. Yes. Now --
Q. No, no. That's -- that was -- that's -- you've answered the question.

Page 67

A. All right.
Q. And then you brought a three-page document, which is a Actavis document, that bears the Bates label 65400 through 65402; is that correct?
A. Yes.
Q. And is it fair to say that we have now reviewed all the documents that you brought with you today?
A. Yes.
Q. But?
A. I believe this document may have been taken from a binder and not been appropriately reinserted because it is a punched document.
Q. Correct. So that's the February 28, 2006 document.
So you're suggesting it may actually go in one of the notebooks that we looked at previously; correct?
A. Yes.
Q. Okay. Now, is it fair to say, having gone through all of these documents, that you have brought -- that the items we've just gone over would be all the information that you would have in response to Exhibit 90, which is the Notice for Video Deposition Duces Tecum?

Page 68

A. Yes. I said something earlier about possibly having five binders. I think this was my fifth. This was the last thing delivered, and --
Q. By this, you are holding up Exhibit 91; correct?
A. Yes. This was the last thing that Pete Miller sent to me by FedEx. I'm not sure why it wasn't in the others, but this is a very key inspection report to piecing together what happened and it was the last piece of information to arrive.
MR. THOMPSON: Let me see if I can satisfy the defendants with regard to the fifth binder. My understanding is that you think there may be a fifth binder. You're not certain.
If I can just simply say, we will go and make a diligent search, and if we uncover a fifth binder that's been placed in another binder, we will make that available to the defense and we will certainly give you an opportunity to question her either by telephone or by reconvening the deposition.
Is that --
MR. DEAN: That's acceptable. Thank you.
MR. THOMPSON: All right.
BY MR. DEAN:

Page 69

Q. And as I understand it, as you sit here today, you're not sure whether there was another binder or not?
A. I'm embarrassing myself that I didn't keep a clear catalog. But I -- when I finished this report, I gathered everything up and I put it over to the side. And I, for some reason, am really -- it's just bothering me.
And so I'm willing to embarrass myself and say, you know, I had this idea there were five, but, to my knowledge, everything that I used for this report is in front of us.
But I would sure appreciate to make sure that I didn't accidentally file this with something else.
MR. THOMPSON: All right.
MR. DEAN: We'll ask you to follow up on that and if you find something, and Mr. Thompson will look at his records, and if there is a fifth notebook, it's my understanding that the defendants will be informed of that.
THE WITNESS: Yes.
MR. DEAN: So we can go ahead.
(Exhibit D-261 was marked for identification.)

BY MR. DEAN:
Q. And just out of the -- for the sake of caution, we have marked as Exhibit 261 the color copy of your report, and I have a copy for Mr. Thompson and for Mr. Kaplan because it may assist us as we proceed here this afternoon.
A. Okay.
MR. DEAN: Harvey.
BY MR. DEAN:
Q. Okay. What do you conceive your role to be as an expert witness in this case?
A. I was asked to comment on two things: The adequacy of the pharmacovigilance processes and the impact on any signal detection in regard to the Digitek case.
It was -- I was asked only on the systems. I was not provided any information on the content, the MedWatch, the PSURs, that would allow me to actually do the signal detection or the trending. The scope of my work was limited.
I was also asked to comment on changes in the risk communication that occurred between the Health Hazard Assessment of Dr. Leikin, the letter to the Dear Customer, the business-to-business letter to Mylan and UDL, and then the public press release.

I could not find any evidence of Dear Doctor or Dear Patient letters.
So when I was asked to look at the changes in those communications, I documented that absence and said, I am going from Health Hazard Assessment to a business-to-business Dear Customer letter, and then the communication to the health care community and the patients is restricted to the press release.
There is not additional communication in the form of Dear Doctor and Dear Patient letters. My comments are restricted to those two spheres and then merged into one document with the supporting evidence.
Q. Does Exhibit 261 contain all of your opinions in this case?
A. This is the conclusion. There are comments in the supporting document that are also expressions of opinions. It is possible that all of the comments in the supporting document have not been completely abstracted to the conclusion.
Because my original intent was to provide this document with this conclusion following this, so that you would go through this seeing the timeline that also notes some of the absences of information, and then the information that I read and

evaluated.
And then when you read the conclusions, that would be the final. And I cannot guarantee you that every single comment in this document has been extracted into the conclusion.
Q. Dr. Frank, are all of your conclusions in Exhibit 261?
A. Yes.
Q. And all of your observations about this case would be included in either Exhibit 50 and Exhibit 261; correct?
A. Yes.
Q. Thank you.
A. Now, please -- yes or no? Okay.
MR. THOMPSON: Just let Dick ask you a question.
BY MR. DEAN:
Q. So we can agree that you did not look at the underlying -- any underlying AER reports on Digitek; correct?
A. I did not receive any MedWatch forms or CIOMS forms. I did not receive any PSURs, any U.S. Periodic Reports, or any other aggregate reports to any health authority.
MR. KAPLAN: I can't hear you.

THE WITNESS: I did not receive any MedWatch forms, any CIOMS forms, any PSURs, ICH PSURs, no U.S. Periodic Reports, or any other form of aggregate reporting to the health authorities.
The only information that I received was Dr. Leikin's final health assessment, Health Hazard Assessment, and FDA -- FDA inspection 483s, Establishment Inspection Reports, and the resultant letters between the FDA and Actavis or Amide.
BY MR. DEAN:
Q. And I don't want to harp on this, but I asked -- this is for furtherance of our proceedings today, I simply asked whether you had received the MedWatch, the AERs and the MedWatch reports.
You told me no. And then you went on and gave me a whole other list of things.
I would simply ask that, as we go along today, you listen to my question and answer my question. Is that agreeable?
A. Yes.
Q. Okay. Thank you.
And so since you did not have the MedWatch forms in regard to Digitek, you would have necessarily been unable to engage in any signal detection analysis; correct?

Page 74

MR. THOMPSON: Object to the form.
BY MR. DEAN:
Q. Go ahead, Doctor. You can answer the question.
A. I'm going to say yes, it precludes definitive assessment. The reason I went on too long with your original question is to list all of the documents that I could recall that contain any information abstracted from the MedWatches.
What I received, and I did discuss this with them last night, was abstracted information that was usually the coding, the ADR coding, that really precluded definitive assessment of any single case and really any aggregate analysis.
Q. So you didn't have the information to do that, did you?
A. No. The only thing I had provided to me was Dr. Leikin's Health Hazard Assessment where I could use the information that he provided in that to assess his conclusions.
But I felt that report did not contain enough detail to allow me to make a full, independent assessment, in that he included only a table of the events and I was not given as an appendix to that the company internal signal detection report that he was

Page 75

provided.
Q. You said a minute ago that you had seen some coding on the MedWatch reports.
What coding did you see and in what document did you see it?
A. The coding would be in the table of Dr. Leikin's Health Hazard Assessments where he has the events. My assumption is that the events listed were events coded.
I do not know that he did not go to the narrative and take out events that were not coded. I am making an assumption. There are similar abstractions in the --
Q. Excuse me. Let me just stop you.
So the only coding -- I want to -- focus on my question.
The only coding was what is in the Health Hazard Evaluation form that Dr. Leikin did; whatever codes appear there are the only codes you've seen on MedWatch reports; is that correct?
A. No.
Q. Okay. What else have you seen?
A. The FDA inspectors, when they go back through the cases, and this is in the supporting documents, when they cite the cases that were not

Page 76

submitted to the FDA, they list events.
The assumption is that when the FDA is talking about adverse events, whether they be 15-day reports that are not submitted or adverse events that -- where they did not like the adequate -- the adequacy of the narrative quality or the follow-up, when they list the event, the date, the drug, and the -- I'm sorry -- the case number, the date and the drug and then the events that follow, the assumption is that that is the coding that was done on the narrative, the events associated with the MedWatch.
They do comment that there were problems with the events being left out of the appropriate box of the MedWatch.
Q. Is what you have described, does it contain actual coding or does it contain -- or is it -- are they documents from which you've assumed a coding?
A. It is an assumption on my part. I have --
Q. So -- so the only -- let's get back to my original question.
The only coding on MedWatches that you have seen is what is contained in the Health Hazard Evaluation form; is that correct?

Page 77

A. And I am --
Q. Is that correct?
A. I have to clarify the yes or no because you --
Q. Well, could you answer first before you clarify?
This is very simple. Have you seen any coding on a MedWatch report on Digitek other than what may be contained in that Health Hazard Evaluation form?
A. I have not seen any MedWatch forms with coding. I made the assumption that Dr. Leikin constructed the table in the Health Hazard Assessments from the coding on the cases.
But I was not able to verify that table against the coding on the MedWatch forms.
MR. DEAN: Excuse me. There's one with just the Health Hazard Evaluation, the document.
BY MR. DEAN:
Q. Dr. Frank, I have -- I hand you --
VIDEO OPERATOR: Your microphone.
BY MR. DEAN:
Q. I hand you what we've marked as Exhibit 220, and it contains the Health Hazard Evaluation form; correct?

Page 78

A. Yes.
Q. And the -- you've been talking about coding. Are you referring to the chart?
A. When you look at the table here -- well, actually, what I'm really referring to is the table.
The column that says, Adverse Events, and they list these, my assumption is that these events will map to the adverse events on the CIOMS or the MedWatch forms and the coding in the database.
Q. And so that's what you meant before by seeing information about coding, you are referencing to this table in Exhibit 220; correct?
A. That, and the FDA inspector's similar abstractions of events that most likely will map to coding on the MedWatch forms and coding in the adverse event databases.
Q. Okay. Let's go on.
How much are you being paid for your services in this matter?
A. $150 an hour.
Q. How much time have you spent on this matter?
A. Initially, I worked to like -- the first week I worked about 35 hours and then I spoke to Smart Consulting about how much time they were expecting.

Page 79

And they said there was no cap.
And I said, well, the convention on -- is either a 40-hour cap, a 50-hour cap or a 60-hour cap. And they instructed me to work to a 60-hour cap.
At the end, I was provided these additional -- the additional documents in a short time frame, and I worked extra hours.
And then I talked to Smart Consulting about whether I should bill over the cap, and they instructed me to bill it.
Q. So as you --
MR. KAPLAN: Instructed you to what? I can't hear you. I'm sorry.
THE WITNESS: I billed over the 60-hour cap.
MR. KAPLAN: How many?
BY MR. DEAN:
Q. So, as you sit here today, how much time have you billed to this matter?
A. I did not do an aggregate analysis of the time. It is included on this, all of the time sheets.
Q. So when we take one of these with us today, when Mr. Thompson and I each take one, we'll have that information; is that correct?

Page 80

A. Yes.
Q. Well, I -- a few minutes ago I asked you about the scope, your understanding about what your assignment was, and you told me the two topics that you were asked to address.
What do you understand your role to be in this case as far as how you present the information?
Do you view yourself as an advocate on behalf of the plaintiffs or do you view yourself as an impartial truth seeker?
MR. THOMPSON: Object to the form.
BY MR. DEAN:
Q. Go ahead.
A. I have particular concern, because this is the first time I've been an expert witness, that my opinions are based on very, very accurate and very, very complete evidence.
I became very, very uncomfortable with the lack of detail in the evidence and the absence of information to -- that I was provided to completely evaluate the systems in the company.
And what I decided to do to make this initial assessment as accurate as possible was to track very, very closely with FDA inspectors'

Page 81

observations that were made by looking at primary documents that I was not provided.
And what I have been hired by the plaintiffs, I want to make sure that my opinions are as accurate as possible.
It's been a little bit embarrassing when you asked me questions and you see that I'm doing -- sketching notes to myself. I don't write out official lists and hand them to the attorneys.
I want as little, I want to say, embarrassment as possible, that will result from my handling what I see as somewhat of a difficult case.
And this being the first time that I've done this, I don't have experience in having done this before. And I have concerns about the incompleteness of the information.
There's a fair amount of additional information, such as MHRA inspections, which are very vigorous inspections on compliance, maybe more vigorous than FDA, and there's at least one of them.
But I think that I made a comment that there were more MHRA inspections.
So there's -- I start to catalog inspection one, inspection two, inspection three, through the timeline, identify them as MHRA or FDA,

Page 82

identify the site, try to specify whether they were actually looking at the pharmacovigilance systems and then map out -- since I don't know what happened from the time the first consent decree was lifted to the first inspections to really put down the facts and start to build a picture of what happened, what failed, what was corrected, what was adequately corrected, what was inadequately corrected, and what was found on the repeat FDA inspection of 2008.

The more that I can get an accurate assessment the course of events, it will allow an accurate assessment of what happened inside the company and any potential impact on signal detection for either Digitek or any of the other products that were dependent on those business processes during that period.

Q. But you've already told us that there's a substantial amount of underlying company documents you have not looked at; correct? Correct?

A. I have -- I'm going to have to say a simple yes.

Q. Right. And then I wanted to get back to my original question.

And I thank you for your answer.

But my original question was how you

Page 83

viewed your role as an expert witness, whether you viewed yourself as an advocate on behalf of the plaintiffs or whether you viewed yourself as an impartial observer relating comments about documents that you had reviewed.

Which is -- which role do you see yourself in, Dr. Frank?

MR. THOMPSON: Object to the form.

BY MR. DEAN:

Q. Go ahead.

A. How do I respond to his objection?

Q. He's made that for the record. You can go ahead and give your answer.

A. Okay. I was hired by the plaintiffs to address very specific issues, to look how these systems potentially impacted signal detection during Digitek recall.

I needed to do -- I'm going to use a legal term -- due diligence in the scope of work that they asked me to meet.

In doing that, I became concerned about the completeness of the information that I was seeing and the fact that my opinion based on that information could be vulnerable if this information that I don't have was brought forward.

Page 84

And I started to function more like a truth seeker. And I don't know how to completely explain.

I'm extremely concerned that the information gathered in the assessment is accurate and complete and can reflect on the signal detection.

And I spoke with them last night, and I will need to talk to Dr. Miller if you need me to give you further detail on my concerns.

Q. But as you sit here, in spite of the questions --

MR. KAPLAN: Mr. Miller? Did you say Dr. Miller?

THE WITNESS: It's mister.

MR. KAPLAN: Pete Miller; correct?

THE WITNESS: No, I'm sorry. Mr. Thompson. Mr. Thompson.

BY MR. DEAN:

Q. So as of today, you have made your concerns about lack of information known to the plaintiffs' counsel and you've done that in the past. I understand that, too.

But you did it again last night; correct?

A. Yes.

Page 85

Q. And you have those concerns, as you sit here today, that you don't have a full and complete information base on which to give your opinion; is that correct?

A. I am privy to some of the information that was obtained in due diligence on drug withdrawals. I'm talking market withdrawals, not recall of the lots.

And the information obtained in the discovery of this case was not as extensive in those cases. And I started to ask about the discovery.

Is this the discovery you would expect to see in a case like this or are the absence of the MHRA inspections? The absence of the company internal signal document, are those issues?

But there apparently was not a further investigation done, and I was told not to start to talk into that direction.

Q. As recently as last night, Dr. Frank, you expressed an opinion to the plaintiffs' counsel that you had inadequate information and concerns about the adequacy of the information to testify today; is that correct?

A. Yes.

Q. Okay. Now, you talked about the

Page 86

adequacy of signal detection. I want to, in the context of Digitek -- and you understand that product was recalled; correct?
A. Yes.
Q. In the context of Digitek, would -- let me strike that.
Your -- one of your expertises is pharmacovigilance; correct?
A. Yes. I've worked in the field for several years.
Q. Correct.
And, typically, in the field of pharmacovigilance, representatives of pharmaceutical companies are looking at a vast array of information to see if new and different adverse reactions are arising from their drugs.
Is that a fair summary?
A. Yes.
Q. And in this case, you -- this case being the Digitek case, you understand that there is a question about a manufacturing defect in the product?
You understand that, don't you?
A. Yes.
Q. And that is -- would you agree with me that's -- it's unusual to address a manufacturing

Page 87

defect through signal detection?
I'm not saying it can't be done, but I'm saying it's not the usual thing you do in pharmacovigilance; is that correct?
A. Classically, signal detection is looking for new events.
Q. All right.
A. But this clustering of cases where the FDA was concerned that they didn't see all of them, any clustering of single cases should alert them to a potential batch issue.
It could be an issue with a site, but it also could be -- could map to an issue with a distributed batch.
And that should have -- be covered by an SOP in the company that will require either a case series or some form of analysis for that cluster of events.
Q. So what you are looking for, what you would be looking for here in terms of signal detection in a manufacturing defect case, is whether -- whether the MedWatch reports were providing information to the company that there might be a manufacturing defect; correct?
A. Yes.

Page 88

Q. Okay. And -- is there a qualifier? Is that, indeed, what you're looking for, what you would be looking for in terms of a manufacturing defect case?
A. With product complaint cases, I was explaining to you that there are often routine Health Hazard Assessments where the pharmacovigilance physician receives work products from quality for the product complaint and the investigation and the analytics.
And then there are Health Hazard Assessments done in realtime where the company pharmacovigilance database is data mined for any cases that could indicate that that manufacturing detect was leading to adverse events that were reported, either globally or particularly in the market of distribution.
Some companies will look at the medical literature, and some companies will go as far as to data mine the AERS database in Washington, which has -- which contains all the MedWatch forms submitted to the FDA, or the WHO database in Uppsala, Sweden, that contains all of the CIOMS forms submitted to EMEA.
But there is typically, for these manufacturing defects that may have gone to market, an

Page 89

assessment of the extent of the exposure, what batches could have been affected, what is the market distribution of those batches, and then is there any evidence that there are adverse events that are resulting in response to the market exposure of those.
Q. So one of the key things that you want to do is to look at the Adverse Event Reports to see if they suggest a defect in manufacture in affected batches; correct?
A. Yes.
Q. And the other thing you mentioned in your prior answer was product complaints.
And so is it also fair to say that if one -- if a company was concerned about a manufacturing defect, they could look to their product complaints on returned product and see -- and make an inquiry to see whether those resulted in any adverse experience reports?
Is that something that companies do?
A. You are correct. The work products fed to pharmacovigilance usually contain an assessment of are there any similar product complaint reports. And that in turn determines the scope of the batches that are potentially affected.
Q. I don't want to interrupt, but I do want

Page 90

to move this along.
What you are looking for -- strike that.
What many companies have is a process by which there's communication between the folks on the signal detection side and folks on the product complaint side where they exchange information to see if it can be useful to the other side; is that correct?
A. Yes.
Q. Is that -- now, did you review the deposition of Sarita Thapar?
A. Yes.
Q. Didn't she, indeed, say that Actavis had such a communication process?
A. Yes.
Q. You have not reviewed the product complaints on Digitek prior to the recall, have you?
A. No.
Q. You have not reviewed the MedWatch reports prior to the recall, have you?
A. No.
Q. So you don't know whether there were any MedWatch reports which even gave off a signal of a manufacturing defect, do you?
A. I went --

Page 91

Q. Would you answer that question, please.
A. The answer is no.
Q. And you don't know whether there were any product complaints prior to the recall that suggested there was a manufacturing defect, do you?
A. I do know about the one from 2004 that led to an investigation. I did not receive the Health Hazard Assessment in association with that 2004 investigation.
Q. Beyond that 2004 incident, which you've talked -- which you just mentioned, have you reviewed any product complaints about Digitek prior to the recall?
A. No. I believe all the ones I saw were post.
Q. So -- right.
So you don't know whether there was -- at the end of the day, you don't know whether there was anything as to Digitek and the manufacturing defect with Digitek to be communicated between the product complaint section and the signal detection section, do you?
A. I went looking to assess what was done, and I couldn't find anything. And then --
Q. Could you -- I'll let you answer however

Page 92

you want to answer, but you didn't -- you did not -- you could not form any opinion as to whether there was communication between the product complaint side and the signal detection side on Digitek as relates to a manufacturing defect because you were not provided with those records, were you?
A. My opinion is not based on the records. When I inquired on the June 2nd meeting and expressed my concerns, I was not given enough to document that process.
But I found in the FDA inspections of 2008 specific statements they were upset about the lack of Health Hazard Assessments.
So what I did in trying to assess whether there was an adequacy, realtime Health Hazard Assessments, because I was not -- I was not provided all of the information that you talked about, even on questioning.
I said, the only thing that I can find that says that there is perhaps something in place, but not in use, was the FDA observation.
And that's documented in here with my comment about concern of lack of ongoing Health Hazard Assessments.
Q. And that's the opinion of one

Page 93

investigator; correct?
A. And I --
Q. Is that correct?
MR. THOMPSON: Object to the form.
BY MR. DEAN:
Q. What you just referenced is the opinion of one investigator; correct?
A. Possibly two, but, yes, one. It's one inspection, probably one investigator, possibly two.
Q. Let me go back. Let me go back. And I want to get an answer to my other question, just so we're clear.
You do not have an opinion as to the actual -- strike that.
You have not had an opportunity to review the information exchanged between -- gathered by the product complaint section and the signal detection section as to -- as to the possibility of manufacturing -- strike that.
You have not reviewed the information obtained by the product complaint section and the signal detection section prior to the time of the recall to determine the adequacy of the information exchanged between the two groups, have you?
A. I have concern that there is an absence

Page 94

of information provided to me at this point in time on which I can base an opinion.
Q. You haven't reviewed that information at this point, have you?
A. No.
Q. Correct? Is that correct?
A. The information that I --
MR. KAPLAN: Is that correct?
THE WITNESS: No, I have not been provided that information.
BY MR. DEAN:
Q. Thank you.
Could you tell us, and I don't want to -- I hope we don't spend much time on this, but I would just like for you to give us a brief overview of your job duties at the FDA, what you did when you were at the FDA.
Could you do that for us, please?
A. I spent two years at the FDA as a fellow in the division of cardio-renal drug products.
And when I finished my fellowship, I was brought on as a GS-14 expert level reviewer in anti-infectives for the small molecules for sepsis and septic shock that had been moved from cardio-renal to anti-infectives.

Page 95

They needed cardiovascular expertise.
I also reviewed things in anti-infective products. I --
Q. When you say "reviewed things," what were you doing?
A. I did IND reviews.
Q. Okay.
A. NDA reviews. I did updated class labeling.
There was a -- an innovative product that had been lax in updating their drug label, and a me-too drug came along, and they approached the FDA about leveling the playing field for competitive marketing by forcing the innovator to update their drug label.
And I was the person who wrote the initial draft of the updated drug label based on all information on the two drugs. And I provided that to FDA supervisory.
I then received -- I also did a workup on an FDA advisory panel recommendation for black box warnings on a class of drug for antimicrobial resistance.
And one of the companies decided to challenge the fact that their drug should be subjected

Page 96

to class black box labelings, and they put together a labeling review and sent it in to the FDA, and I was assigned it and I started on it.
Q. Let me interrupt and see if I can speed this along.
Would it be fair to say that when you were at the FDA, you basically did medical review of INDs, NDAs, and addressed labeling issues?
Is that a fair summary?
MR. THOMPSON: Object to the form.
THE WITNESS: I did. I also did some review of --
BY MR. DEAN:
Q. Just give me the other broad areas that you might -- I don't need the detail, but just a broad area.
A. I did some peer review of -- or I did some review of peer-reviewed literature that came into the FDA for FDA review prior to publication, because there had been disputes between peer-reviewed publications and the FDA in that the peer-reviewed publications were talking too much about off-label use.
Q. Okay. Go ahead. Anything else?
A. I assisted on the placebo hypertension

Page 97

project where they pooled placebo data on hypertension trials to justify the use of placebo groups in short-term Phase II trials demonstrating pharmacodynamic efficacy of hypertensive agents.
Q. At any time when you were with the FDA, did you do an inspection of a manufacturing facility?
A. No. I was not in the -- in that office. I was in the review divisions.
Q. All right. Now, would I also -- from my review of your resume, you are not an expert on manufacturing of drugs, are you?
A. No.
Q. You are not an expert on quality control procedures in regard to the manufacturing of drugs, are you?
A. No.
Q. You are not an expert on quality assurance issues in regard to the manufacturing of drugs, are you?
A. No.
Q. Okay. Have you -- when you were with the FDA, did you have any experience with recalls?
A. FDA, not that I'm aware of. The only thing that I recall are clinical holds on clinical trials.

Page 98

Q. When you were in --
A. There was -- I was made aware of that, but I was not involved with it. I take that back.
Q. I know that you have a work history in private industry as well.
During your time in private industry, did have any experience with pharmaceutical recalls?
A. I did not implement the recalls. I did the Health Hazard Assessments for them.
Q. So that would -- the extent of your involvement with a recall would be to do the Health Hazard Evaluation; correct?
A. Yes.
Q. Okay. Isn't it true that the FDA can ask that a product be recalled for any reason?
A. I will say yes.
Q. Okay. And there is no legal requirement that a product be defective before it's subject to a recall, is there?
A. I do not know the answer to that question. I cannot think of that -- where that is stipulated in the CFR.
Q. Has any company that you've ever worked for received a 483?
A. Yes.

Page 99

Q. Has any company you've ever worked for received a warning letter?
A. Yes.
May I ask a clarifying question?
Q. No.
A. Okay.
Q. What is a 483?
A. A 483 is an FDA form in which the inspectors report their initial observations of the inspection.
Q. Is it a final agency action?
A. It is taken back into the FDA and it produces a warning letter.
Q. Is it a final agency action?
A. I do not know the answer to that question. In legal terms, if it's -- if it -- what constitutes a final agency action. I never --
Q. Did you review any of the 483s in this case?
A. Yes.
Q. Did you -- do you have any recollection of observing on the 483s whether it speaks to that issue that I just asked you about?
A. Yes. It says that it is not a final.
Q. Does it -- do you remember that?

Page 100

A. Yes.
Q. Okay. So you do have some knowledge on that, don't you?
A. Yes.
Q. And you would agree with me that the 483 form itself says it's not a final agency action; correct?
A. Yes.
Q. I take it, you're not -- going from your report, you're not going to testify about issues of adulteration; is that correct?
A. No. They've asked me to be very specific in testifying on issues of these systems and not to go out of scope into issues that would be covered by the cardiologists.
Q. Well, just so I'm clear, you're not going to say that because a drug is adulterated, it's defective? You're not going to offer an opinion like that, are you?
A. No.
Q. Okay. And you're not going to be offering any medical opinions on individual cases; correct?
A. No.
Q. I'm correct, you're not?

Page 101

A. Correct. I am not.
Q. Okay. Thank you.
Would you agree that if the FDA, in its dealings with a company, has concerns about data integrity, it will take aggressive action vis-a-vis that company?
MR. THOMPSON: Object to the form.
THE WITNESS: Please repeat the question.
BY MR. DEAN:
Q. In your experience, if the FDA has questions about data integrity within a company, will it take aggressive actions to follow up with that company?
A. Yes.
Q. In your review of the documents you've been provided, you didn't see any indication that the FDA had any such concerns; correct?
A. There were no explicit statements on data integrity. There were, however, inspection observations of inaccuracies and incompleteness of narratives and coding on MedWatch forms.
Incomplete coding on MedWatch forms can mean incomplete data retrieval on case series and aggregate signal detection.

Page 102

I have not seen any coding conventions from Actavis, and I have not seen any primary documents that would allow me to make any further statement of the impact of coding issues on signal detection.

But the FDA inspector's observation raised concerns about quality issues in the safety database, coding and the case retrieval for signal detection. I can't comment on the extent.

Q. Would you agree that in the context of the AERs that you're testing -- testifying about, the FDA never raised a specific question in regard to data integrity?

Do you agree with that?

A. That term was not in any of the documents that I reviewed.

Q. Do you have any knowledge as to whether a double-thick tablet of Digitek ever reached the market?

Do you have any specific knowledge of that?

A. The only evidence I have that a double-thick tablet reached the market is the 2004 inspection report where a double-thick tablet was returned to the company from a pharmacist in Bellingham, Washington.

Page 103

I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.

But I have no MedWatches, CIOMS forms, or aggregate reports, or any information on the recall product that was incinerated, that would allow me to make any assessment of how many or the percentage of any batch of double-thick tablets that reached the markets.

Q. Is the only one that you are aware of the one you referenced in 2004?

A. There has been reference to a 2008, but I cannot recall that I was provided any documents on that case in 2008.

Q. Do you know whether -- what's your understanding as to double-thick tablets in 2008, if you have any?

A. Something was mentioned this morning. But what I have are the inspection reports and the recall package to finding the batches at risk.

I cannot picture in any documents sent to me any sentence that says X tablet reached the market, X tablet was ingested by a patient or X tablet was returned to the company.

Page 104

Q. Is the only information that you would have in response to my question what would be contained in an FDA document? Is that fair?

A. Unless there is something in -- I was sent sample product complaints toward the end, and I did not loop them in as evidence. They are on the flash drive.

I cannot recall any specifics right now of those. But there may be on those product complaints statements that I do not recall about double-thick tablets. I cannot recall them.

So I have to say no. The only thing that I am absolutely certain that I have seen is 2004.

Q. Okay. And let me ask you a few follow-up questions in regard to that.

MR. DEAN: Why don't we go off the record for just a minute while I find this document.

VIDEO OPERATOR: Going off the video record.

The time is 11:38 a.m.

(Discussion off the record.)

VIDEO OPERATOR: We're now back on the video record.

The time is 11:40 a.m.

BY MR. DEAN:

Page 105

Q. In your report, which we marked, you reference that 2004 --

A. Yes.

Q. -- double thick observation. But you did not reference any follow-up by the FDA.

Did you inquire as to the plaintiffs' lawyers whether the FDA itself did any follow-up on the 2004 double thick observation?

A. No.

Q. Do you know whether the company reported it to the FDA?

A. No.

Q. Would you have expected the company to report it to the FDA?

A. I'm going to say yes, it should have generated a field alert. But I must qualify that, that it's not my area of expertise.

Q. Would this -- would the FDA follow -- would the possibility of an FDA follow-up to this 2004 observation be within one of the white spaces you mentioned before?

A. Yes.

Q. Let me show you Exhibit 20. And I'm going to -- eventually I'm going to direct your attention to a specific page, but generally do you

Page 106

recognize what kind of a document this is?
A. This is an inspection. It's a CGMP inspection.
Q. And was it prepared by -- it was prepared by the FDA; correct?
Look at the back of it.
A. Yes.
Q. And on the front page, on the bottom under Administrative Procedures, it says, We, Investigators Erin McCaffrey and Robert Horan, issued a 482 Notice of Inspection; correct?
A. Yes.
Q. So this is the FDA inspectors inspecting Actavis in 2004; correct?
A. Yes.
Q. In December of 2004; correct?
A. 12/1/04, yes.
Q. Okay. Now, let me direct you -- your attention to Page 6 of this report.
Do you see where it says, Field Alert Reporting?
A. Yes.
Q. Before I ask you the next series of questions, could you just take a minute and read that paragraph, please.

Page 107

A. Yes.
(Witness reviews document.) Okay.
Q. So, first of all, we can agree that the -- in the first two sentences it says that the -- a Field Alert was issued and it was submitted to the New Jersey District Office; correct?
A. Yes.
Q. So Actavis submitted this as a Field Alert to the District Office; correct?
A. Uh-huh.
Q. Yes?
A. Yes.
Q. And then the FDA, when they were there during this inspection, did follow-up on that; correct?
A. Yes.
Q. And the FDA noted that, besides this one tablet, no additional complaints or reports of thick tablets have been received for this high-volume product; correct?
A. Yes.
Q. And they further concluded the event was considered an isolated incident and corrective actions were put in place to prevent its reoccurrence; correct?

Page 108

A. Yes.
Q. And then it says, corrective actions were verified during the inspection; correct?
A. Yes.
Q. And you have no reason to disagree with any of the conclusions reached by the FDA in this Field Alert in regard to the 2004 double thick observation, do you?
A. No.
Q. Okay. Now, is this the kind of document that you would have liked to have seen when you were compiling your report, at least a part of it, in regard to the 2004 double thick issue?
A. Yes. It would have assisted in this timeline, and of documenting corrective actions and adequacy of corrective actions over this period.
Q. Because that's one thing you're looking for; right?
A. Yes.
Q. And here they did -- Actavis did exactly that, they reported it, they took corrective actions, and the FDA was satisfied with those corrective actions; correct?
A. Yes. In December of 2001, it is clearly documented --

Page 109

Q. I'm sorry, December 2004.
A. 2004. In December 2004, this document clearly states that the Field Alert was issued. There was inspection follow-up.
My reading of this paragraph includes that the FDA is actually confirming some of the conclusions of the report that I received. We can verify that point by point if we need to.
And they are saying at that time they consider the corrective actions to be verified. And my assumption is verification means adequate.
Q. Okay. Thank you. Let me get that out of your way.
Have you ever taught or published about pharmacovigilance?
A. I gave internal seminars inside CSC.
Q. Inside what?
A. Inside one of the consulting firms that I worked for. The -- they had approached me about talking at national conventions, but I did not. And, no, I have no publications on pharmacovigilance.
Q. And you've never taught in -- outside of the context in which you just mentioned; right?
A. No. I have never done independent workshops, and I cannot recall ever having done the

Page 110

official company SOP training on pharmacovigilance.
Q. Now, can we agree that MedWatch reports -- the information in MedWatch reports that's received does not mean that a drug caused a specific adverse event that may be described in the report?
A. Yes.
Q. It doesn't even try to do that, does it? A MedWatch report does not even attempt to do that; correct?
A. The MedWatch form does not, but the CIOMS reports contain CIOMS comments.
So in the database, there can be CIOMS comments that will map if the database prints to a CIOMS form, and I do not believe they will map to the FDA 3500, the MedWatch.
But there can be assessments of reporters and company on the MedWatch and the CIOMS, and CIOMS companies assessing all of that information in light of the narrative on the CIOMS and in the database.
Because one of the very important things in a company when you have the databases, there is a reporter's field for causality or relatedness -- relatedness, and there's a company field.
And you want those two to be in parallel

Page 111

and transparent.
Occasionally you hear stories of companies who say we only need one field and the company can overwrite the reporters.
But it is extremely important to maintain two transparent fields with a reporter assessment of relatedness, a company assessment of relatedness.
The company assessment of relatedness may be based on a probabilistic analysis, such as the Naranjo algorithm, and all of that is typically put into a CIOMS comment that also resides in the database.
Q. Let's go back. First of all, a MedWatch report itself does not even attempt to get at the issue of causation; correct?
A. Yes.
Q. Now, you mentioned a CIOMS report. I want to ask you about that. I -- in one of my past lives, I actually knew what those initials stood for, but you're going to have to refresh my recollection.
If you first give me the initials and then tell me what they stand for.
A. I think it was my past lifetime, too.
Q. First, do you remember the initials?

Page 112

And if you don't, that's fine.
A. No. It's a working committee within the WHO that repeatedly analyzes pharmacovigilance practices and publishes recommendations that are available through the WHO in Geneva, but I'm blanking on the actual acronym.
Q. And that's fine. So --
MR. KAPLAN: I think it's S-C-I-O-M-S.
THE WITNESS: It's C-I-O-M-S.
MR. KAPLAN: It's S-C.
THE WITNESS: It's C. Charlie, Ingrid, Oliver, Mark, Sam.
MR. KAPLAN: See what I know? Not very much.
BY MR. DEAN:
Q. And is this a group that takes a number of MedWatches and tries to analyze or synthesize them and issue a report?
What is it that they do? I wasn't quite sure what you were saying that they did.
A. No. They actually do higher level work that actually translates into recommended -- recommendations for best practices in pharmacovigilance.
Q. But they don't take an individual

Page 113

MedWatch report and try to tease out causality from an individual MedWatch report, do they?
A. No. But the CIOMS form is the XUS equivalent of the FDA 3500.
Q. Okay.
A. And when these databases are constructed, the fields are in the databases and there's -- there's a menu that allows the company to print out the FDA form, the CIOMS form for the EMEA, the specific form that goes to the BfArM in Germany, on and on and on.
The same fields in the databases are mapping to country-specific forms. They can submit the CIOMS form to the FDA in lieu of the 483.
Q. In lieu of the AER?
A. In lieu of the MedWatch --
Q. Right.
A. -- 350.
Q. Yes.
A. So there are companies that don't do CIOMS comments because they just submit 350s.
Q. But if a company was to submit the CIOMS report as opposed to the MedWatch 350, that would contain basically the same information that's on the MedWatch, just on another form; correct?

Page 114

A. Yes. Now --
Q. Is that correct?
A. Yes.
Q. And then if it -- so if it contains the same information, it would not attempt to get at causality, either, would it?
A. They do not have a hundred percent concordance.
The CIOMS forms contain CIOMS comments, which are typically a statement of causality, based on the reporter's causality, the medical judgment on the narrative, plus or minus a quantitative probabilistic algorithm on causality, such as the Naranjo.
Q. But you have a number of reviewers that are looking at a particular report; correct?
A. Yes. And there could be discordance in their assessments. And that's why I made the point of the importance of the transparency of the reporter's assessment of causality and the company's assessment of causality.
Those are to be considered independent and recorded in parallel and transparent. And if the company wishes to refute the reporter, they can do so, but they cannot overwrite or obliterate the reporter's causality.

Page 115

Q. Do you have any evidence -- for the purposes of this question, I want to put aside the double thick issue.
A. Okay.
Q. Do you have any evidence that any normal size Digitek tablet reached the market which was out of specification prior to the time of the recall?
A. No.
Q. Okay. Do you -- are you aware that -- are you aware of something called an FDA 484?
A. Would you clarify?
Q. Are you aware that sometimes the FDA will, unbeknownst to a particular company, go out and obtain product from the market and test it to see if it meets specifications?
A. I have heard of that procedure. I have not been formally trained on it, nor have I been formally involved in it. And I was not the recipient of the reports from that procedure when I was at the FDA.
Q. Have you been informed in this case that the FDA indeed went out and tested Digitek that was on the market prior to the time of the recall?
A. No. I have not been informed verbally or in writing.

Page 116

Q. Have you been informed that a company called UDL did -- I'm sorry.
Have you been informed that a company called Celsius did testing on Digitek that was on the market prior to the time of the recall?
A. No. However, I did not, nor did I ask for this. My assumption is that these documents would have routed to an expert witness who was actually expert in that area.
Q. And that's outside your area of expertise, product -- product manufacture and testing; correct?
A. Yes.
Q. Did either Mr. Miller, Ms. Johnson or Mr. Thompson tell you that the plaintiffs' lawyers in this litigation had publicly abandoned the theory of double-thick tablets?
A. No.
Q. Would that surprise you to learn about that?
MR. THOMPSON: Object to the form.
BY MR. DEAN:
Q. Would it surprise you to know that Mr. Thompson has filed papers with the court that says the whole issue of double-thick tablets is a red

Page 117

herring?
MR. THOMPSON: Object to the form.
THE WITNESS: I was not informed of that. I -- I was aware that they were going to pursue the batch uniformity issue, but I was not aware the double-thick tablet issue had been abandoned.
BY MR. DEAN:
Q. Would you have bothered to put any reference to double-thick tablets in your report if you had known that the theory had been abandoned and that plaintiffs were referring to it as a red herring?
MR. THOMPSON: Object to the form.
THE WITNESS: No.
I was asked specifically to evaluate the systems and the impact on the signal detection in the Digitek case, and they were discussing the double-thick tablet and the blend issue, but I was not told the double-thick tablet had been abandoned.
I was not shown the FDA press release stating that there was no risk to public health in the Digitek recall. And I have no information that allows me to quantify the statistical probability of the impact of the blend issue.
These were maintained as abstract risks, and most of the information that I would have needed

Page 118

to determine any probability was redacted out of what I received.

In other words, how many tablets were actually in a batch, what was the likelihood that those batches -- those tablets all ended up in one bottle and ingested by one patient or evenly distributed throughout a -- throughout bottles, one tablet per bottle, which is a different risk.

One double-thick tablet in a bottle is the medical equivalent of a patient accidentally taking a double daily dose.

BY MR. DEAN:

Q. Would you --

A. I have no information on these statistical probabilities or on either plaintiffs' or defendants' assessment of those issues.

Q. Would you agree it would be a waste of time to do signal detection for something that is admittedly a red herring?

MR. THOMPSON: Object to the form.

THE WITNESS: When was it determined to be a red herring?

BY MR. DEAN:

Q. Well, sometime within the last year.

A. If, indeed, it was a red herring, I

Page 119

would agree with you. But the -- there is generally a compulsive nature -- there is generally a compulsive nature to evaluating potential risk.

I have no information on potential versus actual risk, and I do not know at which time potential risk was abandoned.

The investigation of the double-thick tablet from 2004 did not include analytics to allow assessment of suprapotency or subpotent dose of Digoxin. I was also not provided the routine Health Hazard Assessment with that finding.

And let me be careful with this one, I've been trying to assess over the course of this period if there's documentation of recurrence, what percentage of the batch, how is it distributed into the bottles, and all of that information has not been provided to me.

I cannot say based on what's been provided to me that there was no risk.

I -- I really need to be very careful because there's -- there's an absence of information provided to me to be -- that I can independently substantiate the risk of the double-thick tablets or the blend issue, the period of time associated with the risk or the magnitude of the risk.

Page 120

Q. And when you say that, establish a risk from double thick or a blend issue, you don't mean by looking at manufacturing records, you mean by looking at records within your area of expertise; right?

A. Well, as an FDA medical reviewer, we have classes on a lot of this. We don't become expert. But I started to ask questions of the risk of population exposure. Is this one tablet per batch or is it 50 percent of the batch?

There were -- and I'm not an expert on this, but they did a visual inspection of a batch of 3.4 million tablets and pulled out a couple dozen.

I have no idea -- I'm starting to say, what's the risk to a patient population of what the percentage of that batch was that could have potentially been double thick?

Because, to my assessment, the entire batch was not submitted to a validated screening for those double-thick tablets.

Q. You already admitted that you're not an expert in quality assurance or quality control; correct?

A. Yes, but I would have liked them to have sent me something that was quantitative. But there was nothing.

Page 121

Q. So you have an absence of information on that issue; correct?

A. Yes.

MR. DEAN: Okay. Our videotape is almost expired.

Let's go off the record.

VIDEO OPERATOR: Going off the video record.

This is the end of Tape 2.

The time is 12:03 p.m.

(A luncheon recess was taken from 12:03 p.m. to 1:05 p.m.)

VIDEO OPERATOR: We're now back on the video record.

This is the start of Tape 3.

The time is 1:05 p.m.

BY MR. DEAN:

Q. You understand you're still under oath, Dr. Frank?

A. Yes.

Q. Dr. Frank, do you understand that the -- that in this litigation a number of people are trying to recover money as the result of the injuries they allege they received from taking Digitek tablets?

Do you understand that to be the

Page 122

underlying purpose of the litigation?
A. Yes.
Q. Okay. And do you understand -- do you have an understanding as to whether the FDA has spoken on the issue of whether there was likely harm to consumers from Digitek?
A. Last night, Mr. Thompson read the press release to me. I am not privy to the FDA procedures or the extent of the data mining that went on in order to support that statement that there was no risk to public health.
My assumption, having been in the FDA, is that that statement would have been based on all of the existing available data at that time.
But having never worked in that division of the FDA and having not been exposed to those procedures, I cannot comment any further than to say I was read that press release.
Q. Was that -- the answer you just gave me, was that the answer that you were instructed to give last night by the plaintiff's counsel?
A. No. In fact, I brought it up. And they had asked me to be extremely cautious probing into data mining issues.
Q. Did you -- was that your first notice

Page 123

about that FDA statement, last night?
A. Yes. I was kept relatively agnostic as to the present assessment of the actual risk.
Most -- I think that's why I'm somewhat -- I'll use the word "anxious" about my opinions because I've been looking at systems for potential of risk that I've not seen any data that I can independently assess.
And I'm looking at systems where I know what probably the industry standard would be to document due diligence in assessing risk.
And so I'm responding on FDA observations in the absence of some of the supporting data. And having been provided very little data on the actual risk.
So the fact that you are repeatedly presenting me with new information, I expected. I am concentrating on reacting as analytically as I can and as accurately I can in responding as you present me with this new information.
Q. Now, at any point during your work on behalf of the plaintiffs, did you do any independent research yourself on Digitek?
A. No. I was tempted to look at the Congressional investigation, I was tempted to do a

Page 124

Google search, I was tempted to search the FDA web site. I did not.
I left no Internet footprint of my involvement in this case, other than the e-mail trail that the Miller firm and Motley Rice left.
Q. So you did no independent research on your own, outside of that which you were provided, by the plaintiffs' counsel; correct?
A. No. I left nothing on the Google server.
Q. And so let me hand you -- we've been talking about the FDA statement. It's what we marked as Plaintiff's Exhibit 38; correct?
A. Yes.
Q. And this was issued in July of 2009; correct?
A. Yes.
Q. And so this would have been available for -- to you if you had done what you refer to as a Google search. If you had wanted to find this document, you could have easily found it. It's on the FDA web site; correct?
A. Yes. But given the privacy issues of the Google server, I did not do any research on Google.

Page 125

Q. Given the privacy issues?
A. I watch commentary TV occasionally, and I was as affected by one particular documentary on Google that aired in the last few months.
Q. I don't understand the answer. What do you mean?
A. Well, you're asking me if I did an independent search for this.
Q. Right.
A. I could have done it, and if I had been instructed to do it, I would have done it. But if I do a search on Google, I leave a footprint.
And right now you probably know enough about the privacy issues surrounding the aggregate data on these search engines.
So if I'm an expert witness and I'm going out looking for information, I'm creating an electronic trail that right now the legal community is questioning the privacy issues on that server.
So I specifically maintained silence unless I was instructed to go out and do so.
Am I making sense?
Q. I don't understand your answer, but I'm not sure that's important.
A. Every search that I do on Google is

Page 126

there for eternity and they data mine that aggregate data.
Q. Who does?
A. Google.
Q. And what will they do with -- you were afraid of what Google would do with it if you did an Internet search? Is that what you're telling me?
A. People can come to Google and get that data right now.
Q. And were you afraid of what they might do to you if you -- somebody might do to you if you did an Internet search on an FDA web site? Is that what you're telling me?
A. I made an extremely conservative assumption that I was going to maintain electrical silence on this case for the most part.
I think the only thing I did was pull up -- here I need to qualify this, I do remember pulling up Digoxin label. But I did not search Digitek.
Q. Did the plaintiffs' lawyers instruct you not to go on the FDA web site to find relevant information about Digitek?
A. No. I talked to them --
MR. THOMPSON: Object to the form.

Page 127

THE WITNESS: I talked to them about the electrical silence. I asked them not to send me documents by e-mail. And I believe I told them exactly what I was telling you.
And maybe it is completely irrelevant, but I had no idea of the impact. And I have to say, I'll modify it, I do remember going on for one drug label. But I -- no, I made a deliberate decision not to do independent research.
BY MR. DEAN:
Q. You --
A. Even though I knew these documents existed. And if I need to act otherwise in the future, I will. But they were aware of this.
Q. So to retrace my steps before we get back to this document, you are aware that the litigation that we're talking about are people who are alleging injuries from defective Digitek; correct?
A. I know this is a liability case, that they consolidate all of the state-level cases into one federal case. They will be taking deposition on a -- of a panel that will include a couple of federal judges.
Q. But you're aware that the basic allegation is that there was defective Digitek that

Page 128

injured people; correct?
A. Yes.
Q. Okay. And so one key question would be did anyone ingest defectively manufactured Digitek, that would be important in the litigation; correct?
A. Yes.
Q. Okay. And if they did, how much and over what period of time, that would be another relevant question; right?
A. Yes.
Q. Okay.
A. Wait. No, I hope I gave you the right information about my electrical silence.
Q. Now --
A. I think it's irrelevant, but okay.
Q. Now, the --
MR. THOMPSON: It's the most -- that's the most eloquent opinion of big pharma that I've ever heard.
THE WITNESS: It's of Google, actually.
BY MR. DEAN:
Q. Now, you've had a chance to review Exhibit 38 last night, I believe; correct?
A. Mr. Thompson read sections of it to me.
Q. Oh, you have -- so you have just -- you

Page 129

haven't read the whole document then?
A. No. I was told that I would probably be presented with this today.
Q. What sections did Mr. Thompson read to you?
You don't have to read the words. Just tell me the section.
A. I can't find them.
Q. Let me direct your attention and see if I can guess correctly.
On Page 2, that paragraph, was that -- the paragraph that starts Since the detection of the manufacturing problem, did he read that paragraph to you?
A. That may have been one of them. The -- the thing that I remember most clearly about that is a discussion -- we started to talk about my knowledge of the bioequivalence of generics. And, yes, I -- I see that.
I can't remember that specifically because I halted and I started to entrain my own thoughts when they started talking about the bioequivalence and the reliability of generic drugs.
Because I know about all the requirements for bioequivalence and the requirements

Page 130

for 505(b).
But I'm also aware of cases where generic manufacturing has been of variable quality and it has impacted clinical outcomes.
Q. Let me stop you. I want you to, if you can, answer my question.
And that is, what -- what parts of Exhibit 38 did Mr. Thompson call to your attention last night?
Did you see it last night or did he just read parts of it to you?
A. He read it. And when he read me, I was actually worrying about certain things I was going to say today. So if he said something and it would trigger thoughts and I had lapses of attention while he was reading.
Q. Well, sometimes that happens to Mr. Thompson.
A. No. It happens to me a lot because if you say something to me and it kicks off a trigger thought, I will follow it and then I'll come back, and that's why I have you clarify things.
Q. Seriously, you said he made reference to a couple points.
Have you ever read this document before

Page 131

now?
A. No.
Q. Before right now?
A. No.
Q. So this, as you're sitting here right now, is the first time you've actually seen Exhibit 38; is that correct?
A. Yes.
Q. Okay. Now, I want to direct your attention to Page 2 of that document. And the paragraph that's about a third of the way down, which I directed to you before, where it says Since the detection of the manufacturing problem.
A. Since the detection --
Q. Do you see that paragraph?
A. Yes.
Q. Okay. Now, let me ask you some questions about that.
Well, the first sentence says, Since the detection of the manufacturing problems, FDA has been actively engaged with this company to ensure that all potentially affected lots of Digitek tablets have been recalled.
You have no reason to doubt the accuracy of the FDA's statement there, do you?

Page 132

A. I would think they would be extremely cautious in their public statements given the fact that, my understanding, there was a Congressional inquiry on this. I think that these statements have probably been very carefully worded.
Q. So you have no basis -- my question is, you have no basis to disagree with that sentence, do you?
A. No.
Q. Then the next sentence says, In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely.
Did I read that correctly?
A. Yes.
Q. Do you have any basis to disagree with the FDA's public statement in that sentence?
A. No. I do recall this being read. At the time we were trying to access the other documents on his computer. That's what distracted me.
I'm trying to remember how this occurred because we were trying to bring in other documents all at one time. And I made the statement that, yes, they said harm to patients would be very unlikely.

Page 133

And that's where I brought up that you would assume that they would have examined all available data at the time they made that statement.
Because to have made that statement without examining all available data would have left them open to criticism had they been called before Congress.
Q. So you assume that they did examine that data; correct?
A. Yes. But I have -- I have no way to substantiate that.
Q. But it is your assumption; correct?
A. Yes.
Q. Because you worked with the FDA and you know how cautious they are about making public statements, don't you?
MR. THOMPSON: Object to the form.
BY MR. DEAN:
Q. Go ahead.
A. I have no direct experience with this type of procedure in the FDA.
I'm extrapolating from my experience as an FDA reviewer when we would issue clinical hold letters, and what they required of me in reviewing data before I brought forward issues and they would

Page 134

issue a clinical hold letter.
So I'm extrapolating from my experience and I'm making assumptions that they would be engaging caution because of the events of the last half a decade where they've come under increasing scrutiny.
Q. And one of the things it's clear that they looked at before they made this statement was the reported Adverse Event Reports before the recall; correct?
A. That's the data that I'm assuming they data mined from the AERS database.
Q. So they had access to information that you've already told us you did not have access to; correct?
A. Yes.
Q. Okay. So this document, you would agree, was posted on July 9th of 2009 on their web site?
A. Where's the post date?
MR. THOMPSON: I object to the form of that question. I'm not sure how we know that.
THE WITNESS: I can't find the posting date.
BY MR. DEAN:
Q. Do you know -- do have any knowledge as

Page 135

to when this was posted?
A. Not unless it is on this -- I can't -- I can't see the official date on this posting --
Q. Okay.
A. -- like you would have on a press release. No, I can't find it. It might be in my notes.
Q. Do you know whether it's still on their web site?
A. Well, the date it was printed was June 15th of 2010.
Q. So you assume it's still there; correct? Yes?
A. Yes. Uh-huh.
Are you waiting for my response?
Q. No. I'm waiting for me -- myself. I'm waiting to formulate a question. So don't feel compelled to answer any more on my last one.
Would you agree this information about the FDA looking at Adverse Event Reports on Digitek before the recall would have been relevant information to you in reaching issues of signal -- in commenting upon issues of signal detection?
MR. THOMPSON: Object to the form.
THE WITNESS: Yes. Any information on

Page 136

the signal would have been valuable. I think there is a question of the scope of my work versus the scope of the cardiologist's work.
My fixation on the signal has to do with the assessment of the actual risk or any potential risk during this period. But I didn't do the medical evaluation or signal detection.
I'm formulating this because in addressing the issues I was asked to address, I would like to know -- I still think like a medical officer at the FDA. So these became disconcerting issues to me.
And the fact that I was not given documents that someone else may have and I didn't have a fuller picture, and also the fact that the definitive evidence of the recalled drug was incinerated, so there's really no way to ever really know how much of those lots was affected, it left a big void.
So that it became theoretical detection of risk. Did they look? Did they have procedures in place and in use? Were they documented? Were they affected by coding issues?
Because I had no idea what was actually out there to be detected or the things that had been

Page 137

written and been provided to Dr. Leikin or to the other expert witnesses.
BY MR. DEAN:
Q. Let's go back.
You would agree that in the statement that we just read, it's clear that the FDA looked at adverse event information with regard to Digitek; correct?
A. The assumption is that there was a data analysis behind that statement.
Q. Which would have permitted the FDA, at least -- they relied, at least in part, on that assessment in reaching their conclusion; correct?
A. Yes.
MR. THOMPSON: I object to the form of that question.
BY MR. DEAN:
Q. Now, this sentence contained within this document would have provided relevant information to you in regard to formulating your pharmacovigilance opinions, wouldn't it?
A. Yes. And --
Q. And the plaintiffs' lawyers did not provide you with a relevant statement from the FDA that is directly relevant to the pharmacovigilance

Page 138

charge that you were given to answer, did they?
MR. THOMPSON: Object to the form.
THE WITNESS: I was not provided any of the documentation that you are referring to.
BY MR. DEAN:
Q. And you were not provided with Exhibit 38, were you?
A. No. And I did not independently look for it, and I hope that I was not lapse -- lax in trying to seek it independently.
Q. Is this the kind of information in Exhibit 38 that you referred to before as white space?
A. It's a little bit out of the white space, but it is white space for me now that you brought it in. The truth of the matter is, the fact that I did not put this in context by going out and looking, I allowed that white space to occur.
And I did it after discussing -- I believe that I discussed this Google issue over lunch with them.
I don't know whether it was seen as important, but we sort of agreed that the best way to transfer information was either in paper or electronically.
And they never asked me to go out and

Page 139

look for additional information. They provided it to me. So I'm giving you the best of my recollection how this occurred.
Q. The FDA did not say in here that the adverse event reporting procedures of Actavis were inadequate for them to form an opinion about the likelihood of injury to consumers, did they?
MR. THOMPSON: Object to the form of that question. I believe it misstates the document.
BY MR. DEAN:
Q. Go ahead.
A. They report on the lack of reported adverse events before the recall. That is probably valid.
One of the things that I have discussed is that these systemic issues are samplings across multiple drugs, of which one or two out of any samplings are Digitek.
They do contain cases that could be digitoxicity, they could be lack of efficacy. I don't know whether it was digitalis toxicity at normal digitalis levels, supratherapeutic digitalis levels, or in the face of renal failure.
So I can't say anything about the cases I know and I can't say anything about the impact of

Page 140

those two stray cases on the total signal detection.
The FDA says the lack of reported events. These older drugs that have had long market exposure and very little novel adverse events often have underreporting.
And when you do the signal detection, you actually do it on the generic version, even when you're doing it on the branded compound, because people just report the drug.
Q. If you -- let me interrupt you.
If you were doing signal detection for a manufacturing defect, you'd only do it on the product that was manufactured by a given manufacturer; correct?
A. But the reports are often silent from that and that has to be taken into account very carefully, because you don't want to do an inadequate document to be presented in this type of scenario.
Q. Would you agree if you're trying to do signal detection to spot a manufacturing defect, you would look to the product manufactured by that particular manufacturer?
A. When you have the information. But if the reports were silent, the default is to include them rather than to omit them.

Page 141

Q. There's no question pending.
A. There was another point I wanted to make.
Q. Why don't you let me formulate another question.
A. Okay.
Q. Does Exhibit 38 help you fill the void of missing information in this case?
A. Yes. There's -- assuming that the FDA had rigorous review processes before making the statement, in light of the fact that this could end up in a court of law or in a testimony before Congress, this is an important piece of information.
The lack of reported events is impacted by the low reporting rate of generic drugs until it's stimulated by an event such as a recall.
Q. Doesn't this suggest to you, though, strongly suggest to you, that the FDA was satisfied with the adverse event reporting procedures in regard to Digitek before the recall?
MR. THOMPSON: Object to the form.
THE WITNESS: I'm going to be very careful with what I say. Because I don't know if they're required to be silent on certain things.
In other words, they probably did not

Page 142

make an explicit statement of the impact. I'm sure they were very careful about the wording.

But I have no information that would tell me -- I may need to talk to Mr. Thompson before I completely elucidate this, because I told him -- he asked me not to digress into this area, that it was outside of my scope.

And either I should be silent or I should speak to him before I completely comment on -- on this.

BY MR. DEAN:

Q. Well, that's not --

A. It's not permissible?

Q. With the background you've given us, I don't think that's an appropriate conversation for -- to be had at this point. I think you need to answer my question.

A. Okay. I have not been provided any information that says that there was an investigation after the consent decree where anyone went in and data mined the Actavis database.

There's two ways to look at it, what events are coded.

Because at the time of the 2008 inspection, there's still investigator observations of

Page 143

unreported serious cases and there's a statement made by one of the employees about submitting cases from 2006.

Now, the remediation is outlined in the correspondence, including the PSURs for aggregate reporting. And the comment by the company employee talked about how far back they would go.

In other words, they didn't want to go back before the acquisition. And I have no way to completely put that in context.

So there's no data mining -- there's two ways to data mine. One is the coded cases and the other is to say the coding is defective, we're going to text search the narratives.

And what if the narratives are only 50 percent coded? There could be undetected signal.

And in this case, it's unlike some of the other cases I've heard of where they have done those investigations. So I don't know how to comment to you.

Q. Do you think the FDA would have issued this statement unless they were satisfied with the reporting procedures of Actavis in regard to Digitek? Yes or no?

A. I think the answer is yes, but --

Page 144

MR. DEAN: Excuse me. Could -- could you just read back my question and the answer.

(The court reporter read back the following:

"QUESTION: Do you think the FDA would have issued this statement unless they were satisfied with the reporting procedures of Actavis in regard to Digitek? Yes or no?"

"ANSWER: I think the answer is yes, but --")

THE WITNESS: I believe that the FDA was very, very careful to take into account the impact of compliance with reporting procedures by Actavis at the time they issued that statement.

BY MR. DEAN:

Q. And would you agree that if they had been satisfied with those procedures, they would not have issued the statement?

A. I'm going to say yes, but I really don't know.

Q. Okay. Thank you.

Now, you -- a few minutes ago, you talked -- you talked -- you mentioned some product that was incinerated. What did you have reference to?

MR. THOMPSON: Mr. Dean, are you -- are

Page 145

we through with Exhibit 38?

MR. DEAN: I think we are, Mr. Thompson.

MR. THOMPSON: So you're not going to question her on the other four bullet points under that paragraph; is that right?

MR. KAPLAN: Well, I'm going to object to counsel making statements or inquiries here. That's entirely inappropriate.

I move that that be stricken.

MR. THOMPSON: All right. Well, let me then make --

MR. KAPLAN: This is an examination by Mr. Dean. He can ask whatever questions he wants and it's just inappropriate for you to comment.

If you do any more commenting, we're going to be talking to Judge Goodwin about that.

MR. THOMPSON: All right.

Let's talk to Judge Goodwin about the presentation of Defendant's Exhibit to my expert and intimating that this was withheld from her, when, in fact, this is a document that was withheld from us until last week when it was delivered to us from Mr. Anderton, who indicated that he had given it to his expert, but it had not been produced to us.

MR. DEAN: This is not a company

Page 146

document. We're not -- we can have this discussion --
MR. THOMPSON: Well, your testimony -- your testimony to her has begun to intimate that the plaintiffs' counsel has done this and done that.
And, in fact, I'm looking at a document that you've confronted her with which was never produced to us in regular time and which was never available to be sent to her.
MR. DEAN: Never available to be sent to her because it was on the FDA web site?
BY MR. DEAN:
Q. Let's go back to the question that I just asked you about. You, a few minutes ago, used the word "incinerated," I think; is that correct?
A. I will tell you the information, and I don't -- it's probably in here. It may not be. But in the recall packet, they have forms to fill out to send the recalled product to Minnesota for destruction. We can pull that out.
My impression, and I am willing to be corrected if I am wrong, is that there was no analytical work done on that recalled product before it was incinerated.
Q. So you're talking about -- when you say "recalled product," you're speaking about the recalled

Page 147

Digitek in 2008; correct?
A. I think it went from June 6, 2006 through 2008.
Q. Right.
It was announced in 2008, but going back for a couple years. So that -- that's fair. So that was the time of the -- the product that first went on the market in 2006, some of that was recalled.
But your testimony is that when that product got recalled, you believe that product was incinerated; correct?
A. This is why I did this document. I wanted to be very, very careful. I have a fixed idea in my mind from reviewing the documents that this occurred. If I am wrong, I will stand corrected.
Q. Well, what is your understanding as to how much of the product was incinerated?
A. I don't know. I was -- it may be a white space where I was not provided any information on what was done with that product.
But the recall package indicated it would be shipped for destruction, and I was not provided any evidence to say that it was analyzed before it was destroyed.
Q. Okay. Let's go on.

Page 148

Do you have Exhibit 261 in front of you, Dr. Frank?
A. Yes.
Q. Good. Let's see if I do.
All right. I'm on Page 4, which is the first page of -- are you with me there? And it's in the section on Background.
A. Yes.
Q. I want to direct your attention to the second paragraph.
A. Uh-huh.
Q. You reference PSUR preparation; right?
A. Yes.
Q. Here's my question to you, a very simple question: Does a generic manufacturer who distributes product only in the United States have any duty to submit PSURs?
A. Their legal obligation is U.S. Periodic Reports. But the FDA accepts PSURs in lieu of the U.S. Periodic Reports for the aggregate reporting.
So many companies that operate globally produce one PSUR and then it is modified with appendices for country-specific reporting requirements.
Q. Would you agree that if a -- any drug

Page 149

manufacturer, brand name or generic, only distributes product in the United States, they do not have to submit a PSUR, do they?
A. No. If it's just U.S., it can be just a U.S. Periodic Report.
Q. Thank you.
Now, in the third paragraph, you've got some information regarding the company history, do you not?
A. Yes.
Q. Where did that come from?
A. It was abstracted from the Establishment Inspection Reports and from the company correspondence to the FDA, which is where I found the dates, the consent decrees, the day it was -- the defect was lifted in 2001, the dates of the acquisition.
All of this was taken and it should go back to Reference 14, Page 7.
Q. Okay.
A. I tried to annotate every statement in here. If there's an error in my annotation, I will go back and do the due diligence, because these should all be annotated from the documents I was provided. The way this --
Q. No. Let me -- just wait for another

Page 150

question, please.
In the fifth paragraph, the one that starts, There is little or no information, I take it that you were provided no information about either Amide or Actavis -- well, actually, you had the information about the 2004 incident; right?
A. Yes.
Q. So --
A. That was provided -- yeah, that was -- I'm not sure when it was -- when I wrote that, but, yes, there was -- the information became more intensive starting with this February 2006 inspection.
Q. So is it fair to say you have no information before February 2006 about what might be termed alleged deficiencies in adverse event reporting? Is that fair?
A. If you look at the timeline, the first inspection I was able to identify where I don't have the 483s or the reports was in Elizabeth, New Jersey, August 11th, '03 to August 14th, '03.
It was specifically a post-marketing adverse drug experience inspection, and it was classified as NAI.
Q. And what does that mean?
A. No action indicated.

Page 151

Q. And do you believe that what you've marked as Exhibit -- I'm sorry -- it's what is referenced as Inspection 1 related to a company called Amide or related to another company -- or related to a company that was operating in Elizabeth, New Jersey?
A. No. It came from one of these documents that was either an FDA inspection of Amide or one of the correspondences between Amide activists and the FDA.
And so this was within one of the acquired companies, and it was the site. I was -- I was more interested in sites and how pharmacovigilance was moved.
There were two things I was trying to answer: What sites were inspected, what sites were inspected for pharmacovigilance and how pharmacovigilance was moved multiple times?
And was there anything remaining after the consent decree was lifted? Was this pristine at the time the consent decree was lifted and then there was a decline in function, or was there a -- were there persistent issues?
And this was important because it was an NAI inspection in 2003, and it was a very small window of insight, and so I documented it there. And then I

Page 152

would -- if I needed, I would ask for more information to cover that period.
Q. And where did you get the information that such an inspection took place?
A. I can find it for you. Because this was a later edition, and I believe, and I might have to go back and verify, that it came out of this, the introduction of this Establishment Inspection Report.
Q. That's Plaintiff's Exhibit 91, for the record.
A. I had to go through the eyes of the FDA inspectors to find things that I was not provided. And there were some very good historical summaries.
Q. Here's my question for you.
If you can find it quickly, that's fine, but that's a long document. I'm ready to go on to another question if you can't find it.
A. Okay.
Q. Are you ready to go on?
A. Yes.
Q. Here's my simple question to you: On this, what you've labeled Inspection 1, Elizabeth, New Jersey, in 2003, do you know whether that referred -- that that was a inspection relating to Digitek or to totally different product lines?

Page 153

Do you know?
A. No.
Q. Okay.
A. Any --
Q. Okay. You don't; right?
A. No.
Q. Let's just leave it at that, I'll go on and ask you another question.
A. I apologize for my lack of annotation on this.
Q. But whether it was Digitek or some other product that was being commented on, it was NAI which would not raise any alarm bells with you, would it?
A. I put that in there as a pertinent negative.
Q. Okay. Thank you.
Now, then you talk about the double-thick Digitek in July 2004. We've already spoken about that, so I'm not going to question you any more about that sentence.
Then you say, In 2005 there was an MHRA inspection that resulted in an inspection observation on October 25 of inadequate information on transfer of expedited cases.
You were never able -- strike that.

Page 154

Did you ask for the documentation, the backup on that? Did you ask for it?
A. I talked to Pete Miller about this on June 2nd.
Q. Did you ask him for it?
A. Yes.
Q. Did you get it?
A. They were not aware of any MHRA inspection reports in the discovery. I think, if I'm not mistaken, there may have been others.
The fact that there was an MHRA inspection in 2005 implies a repeat inspection in a two-year cycle. But that's an assumption.
But, no, I have no information about MHRA inspection findings other than the fact that one of those was detected at the time of the due diligence in the acquisition, and the decision was made to implement the agreement between Amide and the MHRA after the merger in March.
And there was FDA inspection findings of this noncompliance that sort of coincided with them.
Q. Did you understand this to be a -- first of all, MHRA is a European regulatory agency; correct?
A. Yes.
Q. Did you understand this -- did you

Page 155

understand this reference to the MHRA inspection to deal with a reporting issue as a result of corporate acquisitions?
A. No. But the MHRA --
Q. You did not; is that right?
A. No. This was -- this was before the acquisition.
It was independent, and it was -- I believe it was a finding of the due diligence at the time of the acquisition, and it's the only information I have on the due diligence in pharmacovigilance.
Q. So you don't know what the eventual outcome of that inspection was, do you?
A. There was an agreement, and I know the date of the implementation and I know that it was communicated to the FDA because of concerns with transfer between Copenhagen and the U.S.
Q. Do you know whether the FDA was satisfied with the conclusion on that?
A. This I believe --
Q. Either you know or you don't. Which is it?
Do you know whether they were satisfied or don't you?
A. May I give you an answer based on my

Page 156

best recollection?
Q. First of all, do you know?
A. I believe this came from the Amide response immediately following the 2006 inspection. And the FDA responses reiterated concern with serious underlying systemic issues.
But I can't recall the FDA ever responding to this particular MHRA inspection.
And I inquired whether Digitek was marketed outside of the U.S. and the potential impact of the MHRA inspection on collection of Digitek cases, per se.
And, to my knowledge, and to the knowledge of all the counsel that I had, Digitek is only marketed in the U.S. And so the transfer of these cases from Copenhagen to the U.S. did not impact compliance with Digitek or signal detection.
Q. Did you put that in your report?
You didn't put that in your report, did you?
A. No. It was verbal communication.
Q. Wouldn't a fair and objective expert witness have noted in a Digitek case that an observation about an MHRA inspection didn't have anything to do with Digitek?

Page 157

MR. THOMPSON: Object to the form.
THE WITNESS: Possibly. If I do it again, I'll be more careful with the annotation. I would say --
BY MR. DEAN:
Q. But you do agree that, as you understand the facts now, that Digitek would not have been impacted by that particular inspection; correct?
A. No.
Q. Is that correct?
A. We clarified this, and at this point, my understanding is there are Digoxin cases, but they're not Digitek. That I could assume that all Digitek cases would arise from the U.S.
I have nothing other than verbal confirmation. So I -- yeah, I'll have to say yes. Okay. This is -- I'm pulling in extraneous information trying to clarify.
But it does have impact on the assessment of the systemic issues because they made arbitrary decisions based on this, the implementation of this MHRA agreement, that were upsetting to the FDA and did lead to a 483.
Q. And do you know the final position of the FDA in response -- or in respect to their level of

Page 158

satisfaction with this MHRA inspection?
Are you aware of the final word on that from the FDA?
A. The implementation of this agreement with the MHRA was effective on March 1st. And for reasons unknown to me, Copenhagen sent a batch of cases two to three months later, and it's in one of the response letters.
They made a decision and wrote a note to the file to call their initial receipt date the day they got these from Copenhagen, rather than the date they were first received in Copenhagen.
And the FDA made an observation of that and required the company to make a change, and there's a note to the file of the change in that process.
But they made an -- they made a decision, and I don't know who ratified it, who was given the governance, but the ineffective implementation or somehow the delay in this implementation led to further FDA inspection findings.
Because the transfer did not occur immediately at March 1st. The first transfer was a batch a couple of months later and led to noncompliance. That's sort of why I left it in.
Q. But my question to you is, do you know

Page 159

the final resolution of this in the eyes of the FDA?
A. It was inspection finding that required remediation, and I do not recall any inspectors assessing the adequacy of the corrective action.
Q. Let's turn to Page 5. The second paragraph on Page 5 you recite the history of the warning letters and the responses.
Well, there was a 483 and a response and a warning letter and a response and you recite all that history, do you not?
A. Second paragraph, Page 5?
Q. Page 5.
A. Yes.
Q. And did you -- you've talked before about white spaces. Is there a white space in this paragraph where there is, in all likelihood, a missing document?
A. I documented the missing letters. But it's not -- I don't know that I translated the documented missing letters in here into the conclusion.
This -- this paragraph, there were issues with the accuracy of the responses from February 28th and February 8th, and the FDA took issues with those.

Page 160

But they -- the reason this is in there is they warned the company that these specific violations are serious and they may be symptomatic of underlying problems.
And I was asked to assess systemic issues. And I wasn't given any Digitek subsets, so I started pulling in a lot of things, like MHRA inspections. But the FDA gave them warning.
And I started looking for has anybody given me evidence of the compliance remediation plan, the tracking of it with Metrix, and its adequacy.
So this is put in here because the FDA warned that they needed to assess broader systemic issues.
Q. So at this point, as you read that set of correspondence, as a pharmacovigilance expert, you have a concern that they may not have engaged in the right corrective procedures; correct?
A. Or else I was not given the documents. Because they produced a QSIP, and it's huge, and they said they'd send it to me, that I could look at it.
Q. Who said that?
A. Pete Miller did.
Q. But you -- did you request it?
A. Yes.

Page 161

Q. Did he send it to you?
A. No.
Q. Okay. Now, isn't it -- when you see a history of 483s and warning letters like this, isn't it usual for the FDA at the end of the day, at the end of the sequence, to tell the company whether they've satisfactorily engaged in corrective procedures or whether they're still deficient?
Isn't that commonplace?
A. The FDA revised warning letter, I think this was in July, reiterates the findings, talks about the inadequacy of the response, and this is a quote.
Now, my question is, did the company engage in any type of root cause analysis or process evaluation to assess broader systemic issues, and did they put in place a remediation program that was adequately implemented and tracked.
The bottom line that I came to based on what I could see is they had similar repeat inspection findings in 2008, there was a statement that one of the company -- and it was Mr. Delicato, about cases in 2005, which I thought were part of this remediation.
And I don't know all the circumstances about this or the negotiations or what would be submitted, but the white spaces, what they did, what

Page 162

they did in the QSIP, but the outcome was the FDA said there's a total failure for quality systems.
There's still repeat pharmacovigilance findings.
And then when the recall occurred --
Q. Who said there was a total failure of -- a total failure of what?
A. That's a quote, and that might be --
Q. That's a quote from who?
A. An FDA inspector in either the closeout meeting or in this EIR. And because this is a verbatim --
Q. And, in fairness, that was a quote about total failure of quality control in regard to quality control, not in regard to pharmacovigilance. Do you agree?
A. I was unable to sort out the quality unit. It -- for the most part, it was addressing manufacturing issues.
But my question is, there's usually quality systems that control pharmacovigilance quality and product complaint and clinical research.
There should have been some sort of a quality system for all of these business critical functions.

Page 163

Q. Can we agree that if there is a letter from the FDA to Actavis saying that they were satisfied with the company response to the pharmacovigilance issues contained in the warning letter of August 15, 2006, you've never seen it, have you?
A. No. I've not -- I did not see -- I did not identify in my review any interim FDA communication that said they were satisfied. If it's my error, I stand corrected. There are letters that I was not provided, and I documented that.
Q. Did you -- how did you document what you were not provided? How would you know how to document it?
A. Oh, boy. I laid out this timeline for myself. Inspections I found are in red. Any information I have on the inspections was there unless there was a full report.
In blue were the company's responses. And the black are these intercurrent communications. And here in the timeline is part of my attempt to document things that were not included to me.
Q. Let me hand you what we marked as Defendant's Exhibit 87.
A. All right.

Page 164

(Witness reviews document.) Okay. They --
Q. You've never seen this document before, have you?
A. No.
Q. And we can agree that it is a letter from the FDA to Actavis Totowa dated January 3, 2007; correct?
A. Yes. And I don't have this in the white space, so I have no indication this letter existed until you just gave this to me.
Q. This is the first time you've ever seen it in your life and the first time you're even aware of its existence; correct?
A. Yes.
Q. And we would agree that it says, in the second paragraph, New Jersey District has reviewed your response regarding adverse drug experience reporting deficiencies. Your corrective action and the revised procedures appear to be satisfactory.
That's what it says; correct?
A. Absolutely.
MR. THOMPSON: I object to taking that out of context.
BY MR. DEAN:

Page 165

Q. So the -- in your paragraph on Page 5, you referenced the 483s and the warning letters on the pharmacovigilance issues, but you didn't reference Exhibit 87 because you were unaware of it; correct?
A. Yes. I expressed concerns multiple times about missing information like this that could impact on my --
Q. And it's clear that the FDA was satisfied with that response, wasn't it?
MR. THOMPSON: Object to the form of the question.
THE WITNESS: Well, the FDA is satisfied. I don't know -- August 15th. Revised warning letter.
Wait a second.
We acknowledge dated September 6th, the company responds, the procedures, I don't have October 26th. There is a clear statement that corrective actions and the revised procedures were satisfactory.
BY MR. DEAN:
Q. And you don't have any basis to disagree with the FDA position on that, do you?
A. The company --
MR. THOMPSON: I object to the form of the question.

Page 166

THE WITNESS: I do not believe I've seen the additional revised procedures on October 25th, and so I cannot make an independent determination.

And in order to really give you an accurate opinion, I should probably read -- re-read the September 6th.

However, I think that in a court of law, this FDA opinion would supersede my opinion unless I could really provide evidence to the contrary.

BY MR. DEAN:

Q. Thank you.

So as of January 3, 2007, we can agree that the FDA was satisfied it had received all adverse reaction reporting from Amide or for Actavis Totowa that had been raised by the 483 and the warning letter; correct?

MR. THOMPSON: I object to the form of the question and I entreat Dr. French (sic) to please read the entire document before she answers a single out-of-context sentence.

MR. DEAN: It's Dr. Frank, I believe.

MR. THOMPSON: I -- then I've just -- I'm probably in the wrong place at the wrong time.

THE WITNESS: This is very, very difficult because these corrective actions have a

Page 167

scope. And I'm reading this out of context in the scope, so I can't track what the corrective actions were or the procedures.

And I have no information about the adequacy of the corrective actions during the future inspection because there's both the plan and the implementation of the plan.

So this is basically saying they did -- they did a corrective action. And the District Office found it satisfactory, and I'm assuming that they could implement it without revision.

BY MR. DEAN:

Q. Earlier, much earlier this morning, you told us that what you were relying on this -- in this case was the FDA conclusions and not the underlying documents.

Do you remember that?

A. Yes. There is -- I've not -- I don't have a lot -- I just read 483s and established inspection reports and letters.

Q. And so this is no different. This is an FDA document with a final conclusion and you have no basis to disagree with it; correct?

A. Not at present.

Q. Okay. Thank you.

Page 168

MR. DEAN: Do you want to keep going or do you want to take a short break?

MR. THOMPSON: I think we ought to take a break as we go, you know.

MR. DEAN: I think we've been going about an hour. Let's take a short break.

I don't want to take a long one.

MR. THOMPSON: Sure.

MR. DEAN: Let's go off the record.

VIDEO OPERATOR: Going off the video record.

The time is 2:06 p.m.

(A recess was taken from 2:06 p.m. to 2:16 p.m.)

VIDEO OPERATOR: We are now back on the video record.

This is the start of Tape 4.

The time is 2:16 p.m.

BY MR. DEAN:

Q. Dr. Frank, in regard to Exhibit 87, we've -- before we broke, you agreed that this provided relevant information on the status of the adverse event reporting at Actavis; correct?

MR. THOMPSON: Object to the form.

THE WITNESS: I think it's an important

Page 169

piece of information that I would have liked to have had when I -- when I came up with the conclusion.

I'd like to put it in context with the decision to move pharmacovigilance from Totowa to Elizabeth, because Elizabeth apparently was compliant.

Remember I told you about that NAI inspection. It's a very, very important piece of information that could -- it clearly has a material impact on the analysis. I cannot immediately put it in context with the overall picture.

I'm assuming that you're going to continue to present me with further information that's extremely important to the assessment. But I do not deny that this is important.

BY MR. DEAN:

Q. Well, your first conclusion -- your first basic conclusion, as I understand your summary of your report, was that there were -- it's not clear that there were appropriate pharmacovigilance procedures in place at Actavis Totowa; is that your -- a fair summary of one of your primary conclusions?

A. The original assessment in the response letter talked about the inadequacies of the interpretation of the regulations and an implementation of the procedures.

Page 170

Q. Now, let me interrupt you. I'm not talking about what was in the letter. I'm talking about the summary you gave me this morning about the two key points you were --
A. Yes.
Q. -- trying to make in your report.
And one, I think, was the adequacy of the pharmacovigilance procedures and its impact on signal detection and that you were asked to evaluate the system that was in place; correct?
A. As much as possible, yes.
Q. And would you agree that this document establishes, at least in the eyes of the FDA as of January of 2007, that appropriate procedures were in place?
MR. THOMPSON: Object to form. I think it mischaracterizes the document.
THE WITNESS: It establishes that appropriate corrective actions were presented to the agency and that the revised procedures were satisfactory.
But it does not establish that there were satisfactory procedures in place during the total period affected.
BY MR. DEAN:

Page 171

Q. Well, your opinion about inappropriate procedures was based upon -- primarily upon the series of 483s and warning letters in regard to pharmacovigilance, wasn't it?
A. Yes. The assessment I made was only on what I was provided in the 483s and Establishment Inspection Reports and responses.
Q. And so the primary -- that was the primary basis. And now you see Exhibit 87 for the first time which gives the FDA's final response to that series of observations and warning letters.
And my question to you is --
MR. THOMPSON: Object to the form.
BY MR. DEAN:
Q. -- would you like to revise your opinion stated in your report about the adequacy of the procedures at Actavis for pharmacovigilance reporting?
A. I think that there were definite issues uncovered during the 2006 inspection. There was a shift from 2003, which was NAI, to 2006. And then there was a response letter talking about inappropriate interpretation.
I think -- I think the important thing is to look at the actual wording. But the February 8th, 2006 response talks about problems with

Page 172

interpretation of the regulations.
And I believe the specifics were in actually assessing 15-day alerts.
I think everything was stamped as a 15-day alert and sent in without assessment of seriousness or expectedness. There were issues documented at the inspection and by the response letters that required the corrective actions.
Q. Here's my question. It's a very simple question. Would you like to revise your opinion in light of Exhibit 87?
A. I can't completely because they required corrective actions, which implies deficiencies, either in the procedures or in the compliance with the procedures.
So there was an issue that required corrective action and required the revision of the procedure.
It's the revised procedures that are satisfactory, not the ones that were revised. Not the baseline.
So I have to be very, very careful and think -- I mean, for me to completely revoke everything looking at one letter and not sitting down and carefully analyzing it is a little dangerous.

Page 173

It's as dangerous as making an opinion on inadequate information.
Because this -- the fact that there were corrective actions and procedures that were revised implies that there were problems that required the corrective actions in the revision. The FDA was okay with their plan.
We do not know because we don't have the FDA confirmation of the adequacy of the corrective actions in a future inspection.
If, indeed, this 2008 inspection that had me concerned correlates to this confirmation, then we have some observations consistent with inadequate implementation of this plan that they approved.
So right now, this is very, very important.
Q. This being 87?
A. And potentially would modify it.
Q. Number 87.
A. But I still see that it's a -- it's a -- still a complex and confusing chain of events where a company was on consent decree, they came off, they had apparently clean inspection in 2003, and then things started to happen that required corrective action.
Do we know that it was corrected, or was

Page 174

it corrected all by transferring to Elizabeth? I can't answer that at the moment.
Q. Is it fair to say that Exhibit 87 raises significant questions in your mind as to the -- as to your opinion and that you would need more time to think about the issues and look at the underlying documents in order to stay and maintain with your opinion?
MR. THOMPSON: Object to the form.
THE WITNESS: I would like to be able to include all of this new, important evidence in a revised opinion and revise the white space. Because there could be more vulnerabilities.
And I hope that's not too much of a hedge. But, yes, this should be incorporated into the -- into the opinion, but with very careful analysis.
BY MR. DEAN:
Q. Now, is it fair to say that as of January 3, 2007, the actual MedWatch reports that were mentioned in the 483 and the warning letter, isn't it clear that those had been submitted to the satisfaction of the FDA for this letter?
A. This is where I got really --
Q. Isn't that clear to you?
A. It's not clear based on the totality of

Page 175

the evidence. And it might be -- I want to show you why, if I can find quickly. I can't search this electronically, but it's back in the 2008.
I saw their agreement with the FDA for the remediation of the lack of compliance with the U.S. Periodic Reports. And that was approved, I think, actually by Washington. I should clarify that.
But there's a statement back here, and I think it was the closeout, the minutes of the closeout meeting, where they're going back and talking about submitting reports from 2006.
And I went -- that's when I really got worried and I do not yet have a clear picture of the events from 2006 to 2008.
Why are they confronting them in 2006 -- in 2008 about reports that were to have been submitted as part of the remediation in 2006, and the company is making a statement about not sure how far back they would go.
I have no insight to that.
I know that they initially did not want to remediate anywhere before they acquired, and I don't have a lot of insight into the regulatory risk decisions that were being made or why they're saying they have to discuss internally what will be

Page 176

submitted.
I can't tell you based on what I've seen if this initial satisfactory answer does not have to be modified based on what happened in 2007 with the confirmatory inspection. I'm sorry.
Q. You've told us before, if I'm correct, that it's -- you were uncomfortable in your role in this case because you didn't have full information and that it was -- I think your words were, it was dangerous to make an opinion based upon inadequate information.Do you agree with that?
MR. THOMPSON: Object to the form.
THE WITNESS: I think -- I actually think I said that. It may have been a mistake to say it. I think part of it is -- I do.
BY MR. DEAN:
Q. You agree that you said that; right?
A. Yes.
Q. And isn't that exactly where we're at here because you're saying that there -- that Exhibit 87 raises significant questions, but you have inadequate information to totally evaluate the impact of Exhibit 87? Is that fair?
A. Yeah, I think --
Q. Is that fair?

Page 177

A. I think at that point I was provided information and I discussed this with counsel. What if they -- I have all of these questions, and I think there's information out there that they will present to me.
What happens -- and I asked this at the June 2nd meeting of Megan Carter. What happens if I'm provided information that is material and requires me to modify my position?
They said, we'll take it and revise the position, but we want a preliminary assessment.
Q. Do you understand that these opinions have been filed with the court?
A. Yes. I talked to them about this.
Q. Were you concerned about that?
A. Yes. I expressed that.
Q. And was your concern that you didn't have enough information on which to base an informed opinion? Was that your concern?
A. I was concerned that I had incomplete information where I would be vulnerable to being presented with further information that could lead me to modify my opinion.
Q. And it turns out that that's happened and that you may well want to modify your opinion; is

Page 178

that correct?
A. Possibly.
Q. Okay.
A. But the -- this does not yet explain away the 2008 observations and the statements that the company employee made about persistent nonreporting of cases in 2006.
So while it's material, I don't think it can completely negate because --
Q. Let's -- I'm sorry. You go ahead and finish. I want to talk about that in a minute, but I want you to finish.
A. What is distilled down was 2006, the remediation program, and persistent observations in 2008, and this unexplained comment about submission of cases that apparently were to have been submitted as part of the 2006 remediation.
So that is still -- and here I'm coming back to this, I asked them -- I told them this specifically, I said, this would be the basis of my opinion. And yet, all of this has not been taken into account. Should I proceed with this?
I asked them very seriously what constitutes adequate documentation for the opinion, how much they can provide for me, how can -- how much

Page 179

I can request on any further discovery?
I asked for a lot of guidance, and I trust that they gave it to me appropriately, is in taking the information they gave to me, what constituted a legitimate opinion before this was filed.
This was not done haphazardly. I actually tried my best to render an opinion based on what I was granted.
Q. But, as we sit here today, you are -- the fact of the matter is, you -- at the time you rendered it, you were concerned about inadequate information.
And now, as we sit here today, you have an even greater concern about inadequate information being provided to you in order to formulate this report; isn't that true?
MR. THOMPSON: Object to the form.
THE WITNESS: You've provided me exactly what I anticipated might happen and what I raised to the people that hired me and asked me to do this analysis for them. This is not unexpected.
And I asked them how I should handle it and the risk and how I should respond to it when it occurred. And they said, what you do is you take

Page 180

this -- we have to take this and revise the opinion.
If I was given advice, please forgive my naivete, but I really made an attempt to deliver a -- an adequate expert witness opinion given the circumstances.
BY MR. DEAN:
Q. Dr. Frank, isn't it fair to say that you are no longer comfortable in much of the information in your report?
MR. THOMPSON: Object to the form.
THE WITNESS: I think it requires revision based on new evidence. Yes, I'm -- I -- I think there's some things, such as the point -- time point in 2006 and the time point in 2008, that says there were problems with that.
But I still do not have any real insight into the QSIP, and I only have a few observations in 2008.
And, yes, I think there's a great deal -- I think the -- I think that the comments on individual observations probably refer well back to the individual observations.
But the absolute conclusions probably need to be modified based on the evidence that you've provided me.

Page 181

BY MR. DEAN:
Q. And while I recognize -- while recognizing that the preparation of a report is an ongoing process, did you -- were you informed that the report that was filed with the Court was supposed to be a final report?
Were you ever told that?
A. I was told the deadline and I was told it would be reviewed. And I asked what I would do in this scenario. And I did have some discussion of the risk of this occurring.
I assumed -- I -- no, I completely anticipated you would do this.
This is why I'm receptive to it, and I'm very, very careful to look at it analytically to -- to accept what has to be accepted, but not to be foolish and under a state of anxiety back down when I need to be careful and analytical.
I can err in either direction in this setting and I want to be very, very cautious.
Q. Let's go to Page -- go back to Page 5 --
A. Okay.
Q. -- in the one, two -- third paragraph.
A. Yes.
Q. I want to get on to this reference to

Page 182

Mr. Delicato in 2008 that you've mentioned before and try to get into the right set of documents and ask you some questions on that topic. Okay?

A. That's fine.

Q. Now, I think it's in the second sentence of that paragraph.

It says, In addition, there are implications of the FDA observation that, quote, Mr. Delicato stated that unreported cases from January and February 2006 would be submitted to the FDA.

However, Mr. Delicato informed me that they did not have a definitive answer to how far back they would go in reviewing unreported cases. He said they would include this information in their written response to the New Jersey District.

What -- is that a -- so that's from Reference 15; is that right?

A. And it's in quotations and it's very carefully placed there.

Q. Hang on. Let me see what 15 is. Okay.

So 15 is a May 2000 -- May 21, 2008 FDA inspection report; correct?

A. Yes.

Q. All right. So let's get that in front of us.

Page 183

I am handing you, Dr. Frank, what's been --

VIDEO OPERATOR: Your microphone.

MR. DEAN: Sorry. Thank you.

BY MR. DEAN:

Q. Dr. Frank, I'm handing you what has previously been marked as Defendant's Exhibit 62.

And the first page of this is a letter from the FDA to Mr. Delicato, but attached to that is, I believe -- will you agree attached to that is the May 21, 2008 report that you're referencing?

Are we talking about the same document?

A. Yes. May 21, Reference 15. This is -- Reference 15, Page 8. Well, Reference 15 in my bibliography is an FDA 483.

Q. Oh, I'm sorry.

A. No. This may be my error and the fact that I had to redo this bibliography in short order because we merged the documents.

Q. I -- well, let's -- this exhibit, we can agree, is the EIR from May 21, 2008 inspection; correct?

A. Yes.

Q. And so you're saying your reference -- and, in fairness, Dr. Frank, on the top of Page 3 of

Page 184

15 of this document, it says, On May 21, 2008, I issued a Form 483 inspectional observations to Mr. Delicato.

So it looks like there was a 483 issued that day, and the Establishment Inspection Report, I don't know when it was prepared, but, obviously, there was an inspection that day that resulted in the 483 and the generation of this -- the EIR.

Would you agree with me there?

A. Yes. And there's also May 20th closeout minutes from which they may have been taken.

Q. Now, do you know -- well, first of all, can we find -- I'd like to find where you're quoting Mr. Delicato.

Would that be in a 483 or would that --

A. No. That's why --

Q. That's probably going to be in the EIR, isn't it?

A. Or in the May 20th closeout minutes. They met with management the day before they issued the 483. There's -- it's May 20th, 2008. And there was some background in there, and I think there was that statement.

Q. Can you find -- let's see if you and I can find this statement.

Page 185

A. I don't know the background of it, that's why it concerned me.

MR. THOMPSON: Is it important for us to hunt through, or can I point you all on it?

MR. DEAN: Yes, if you've got it. No, show me.

MR. THOMPSON: It's on Page 8 of 15, right at the end of that long redaction.

MR. DEAN: Thank you, Fred.

BY MR. DEAN:

Q. Do you see that now?

A. Yes. And it was at the closeout meeting that he stated this. I have no information as to the background of that.

But there's apparently still unreported cases from January, February of 2006, which seemed unusual because they did aggregate -- they had -- they had --

Q. Let me stop you. You're talking about a closeout meeting -- strike that.

There was a closeout meeting in regard to Digitek for Actavis Totowa; correct?

A. There was an inspection in Actavis Totowa from April 21st to May 25th, and I believe it covered more than Digitek.

Page 186

I have no way to know whether these cases, unreported cases, were Digitek or another product or the impact on the Digitek case.

There's cases that were supposed to be part of the remediation. Apparently, they're not submitted. I don't know what they are.

I don't know whether there was regulatory risk decision taken by the company. But this statement -- am I talking too much?

Q. No, no. I think we're actually getting to the bottom of this. I think we're going to get there in a minute.

So you -- you don't -- first of all, on the quote here on the bottom of Page 8, you don't know whether any of those related to Digitek, we can agree on that?

A. No.

Q. Pardon me?

A. Very little of the information --

Q. Can we agree on that?

A. Yes, we agree on that.

Q. And if you turn the page to Page 9 of 15, would you agree that there is, again, reference to the Denmark site forwarding reports to the Elizabeth site and for processing submission to the FDA?

Page 187

That's what it says, doesn't it?

A. This is the bulk submission from 2000, July and August. That was the implementation of the March 1st MHRA agreement. Yes, that is what that is.

Q. Do you know one way or another whether this exhibit and its observations about AERS, do you know whether it is solely focused on foreign adverse reaction reporting?

A. If you're talking about B here?

Q. I'm talking about Exhibit 62. I'm talking about the EIR, dated May 21, 2008, submitted to Actavis Elizabeth, LLC.

A. No. I do not know whether this is all foreign reporting. I think that --

Q. Let me ask you this, then. Are you aware that there was also, I think, an Establishment Inspection Report on Actavis Totowa dated May 20th?

Have you ever seen that?

A. Yes. I have those two inspections that occurred simultaneously, and I spent a fair amount of time sorting between the two of them.

Q. Okay. But the one you quoted from is -- the one you quoted from on Page 5 of Mr. Delicato is from the --

A. Yes.

Page 188

Q. -- May 21 inspection of Actavis Elizabeth.

We can agree on that; correct?

A. Yes.

Q. And you've already told me you don't know whether the events that are being described in here are simply related to foreign reporting or not, you just don't know one way or another?

A. Well, the foreign reporting they're talking about the July 2006 and August. This is when Denmark sent them a bulk of cases. Probably most of them should have been in March and April. But I can't -- I don't know about the distribution.

But then they're going back and talking about late cases. And there's -- the information in here, there may be information in the coding that tells -- the case code that tells whether they're a foreign report.

But I don't know enough about the case codes to tell.

Q. And all this -- on Page 8, all this really says is that Mr. Delicato said at the closeout meeting of the Actavis Elizabeth inspection that they did not have a definitive answer as to how far back they would go in reviewing unreported cases.

Page 189

It wasn't a submission issue, it was a review issue; is that right? Is that the way you read it?

A. Well --

Q. Take your time. I want to be fair.

A. There was something else that was left outstanding in my mind, and I --

Q. First -- I want to get to that. But, first of all, is it fair to say that this comment reflects that everything had been submitted, but there was just an issue as to how far back they would go in reviewing those cases?

A. The way he stated it, there were still unreported cases outstanding from January and February 2006. I don't know whether they're foreign. I don't know whether they're U.S.

I don't know whether they were cases that were cited in the inspection report or -- there's no specifics.

Q. Okay. All right.

A. I can't -- I can't state that. And I don't know what the how far back means.

I had an outstanding question in my mind that the acquiring company really did not want to put resources into remediation of issues that existed

Page 190

before the time of the acquisition, and they were attempting to negotiate this with the health authorities.

If I did not adequately document that in my report, I stand corrected. But there was still some question in my mind whether they were making calculated regulatory risk decisions.

And that, when he said how far they were willing to go back, I can't comment any farther on that.

Q. You don't -- again, this is an area, in your mind, where there's missing information; is that fair to say?

Is that yes?

A. Yes.

Q. Now, and you are also -- you are unaware as to whether subsequent to that comment what follow-up there may have been and what the regulatory response may have been in regard to that observation; is that fair?

A. I have not seen any subsequent documentation to give further insight into these -- into this.

Q. So that's more missing information; correct?

Page 191

A. Yes.

Q. Okay. Dr. Frank, as of January 3, 2007 when Exhibit 87 was issued, are you aware of any unreported MedWatch report on Digitek?

A. There are inspection observations prior to that, 2007.

Q. Listen to my -- listen to my question.

A. Yes.

Q. I know that we've talked about issues that they had in 2006.

My question is, as of January 3, 2007, are you aware of an unreported MedWatch report in regard to Digitek?

A. That's a very important question, but there's a couple different ways to interpret it.

Q. Well, are you aware of the existence of such a report?

A. I'm aware of unreported cases in the initial inspection observations. I'm aware of the agreements.

But I don't have any kind of documentation that allows me to track the cases in the inspection observations with the remediation and submissions.

Q. So --

Page 192

A. I can't tell you whether the implementation of the -- of the remediation -- and there may be -- there could be blanket statements, and I'm just not -- I'm trying to be really accurate here.

Q. And that's fine.

A. There could be statements that somebody said, yes, it was adequate, but I can't go through here quickly and find them.

Q. And my question is, are these -- I asked you whether you were aware of any set of circumstances which should have been reported as a MedWatch, which wasn't as of this date, and you referenced the later observations in the 2008 inspection; right?

A. They're the ones in which I was concerned about.

Q. If you put those -- if you put those aside for the moment because we just talked about those --

A. Yes.

Q. -- and you already told us you're not sure whether those are Digitek or not; right?

A. Absolutely.

Q. So put -- so we've explored, I think, Exhibit 62.

So if you put it aside for the moment,

Page 193

are you aware of any unreported set of circumstances that would give rise -- should have given rise to a MedWatch report in regard to Digitek as of January 3, 2007?

A. No. The only --

Q. Was that a --

A. That was a no. The only observations we have are the inspection reports, 2006, and the repeat inspection. My information does not allow me to track the actions of Actavis in fulfilling the response letters.

Q. So you can't testify, as of any point of time after January 2007, that there was a set of circumstances that should have been in a MedWatch report that was not reported; you just don't have an appropriate information base to do that, do you?

A. There were specific cases in 2008 in this. They were Digoxin. I don't know whether they were Digitek.

Q. You don't know?

A. It's Digoxin, but I think they have some sort of XUS Digoxin that I'm not to take into account.

Q. You are in --

MR. DEAN: For the record, the witness is in Exhibit 62 now.

Page 194

THE WITNESS: Yes.
BY MR. DEAN:
Q. And there's reference on what page to Digoxin?
A. This is Page 9 out of 15, and there's clearly a Digoxin case there.
Q. Right.
A. But it's not brand Digitek. And I don't have any -- I didn't get any written documentation that -- I know they have from the -- from some of the other depositions, they have XUS Digoxin, but it's not Digitek.
And I repeatedly clarified whether XUS cases should be brought into this assessment, and I've been told no. Okay.
Q. And just for the purposes of time here, you don't know whether this reference on Page 9 of 15, whether that reference to Digoxin tablets references Digitek or not, do you?
A. No. We need to know this case number. That will code the country of origin of the case.
So it is possible to tell whether that's a U.S. case that was just reported as the generic and should be taken into account, or whether it's potentially an XUS case.

Page 195

Q. So, as you sit here today, you're not aware of any -- you don't have any specific facts that there was a set of circumstances in regard to Digitek after January 3, 2007, which was not appropriately reported in a MedWatch; is that correct?
A. The only thing that I have are these inspection reports.
Q. Being --
A. And my answer at this point, my preliminary answer is, no, I cannot identify it from memory.
Q. Let's go on to another topic here.
Are you done with that one? Yes, let's get those out of your way.
A. Okay.
Q. One of the topics you address in your report is the -- what I will call the recall communications.
A. I was asked to specifically look at those and the change in the patient population at risk.
And I was provided the attorney's initial assessment that from the -- from the Health Hazard Assessment to the letter to the customers to -- which are the business customers, which is Mylan, to

Page 196

the press releases to the public, there was a change in risk population.
I brought up the issue that at least in writing informed consents in clinical trials, we write to a fourth- to fifth-grade comprehension level.
And that when they wrote the press release, there may have been that process to modify the communication. I did not put that in my report.
But what I did was, I tracked the changes in patient population, which did change from the Health Hazard Assessment to the final communication, and the changes in the patient population at risk, and I commented on that.
I was asked to comment, and I thought there was clearly a change and it clearly changed the total patient population that would be warned. And that's pretty carefully documented, those changes with quotes.
I did not speculate on why it was done, on any data that would have supported the removal, because I had no access to that.
But they did go from a larger patient population at risk to a smaller patient population at risk by the time they released the press release.
Q. Okay. First of all, would you agree in

Page 197

terms of the recall communication, it was clear to everyone that the company wanted the product back and off the market and no one should be taking it?
A. Yes.
Q. Okay.
A. A recall is a recall.
Q. Right.
So anyone who, whether they were a patient, a pharmacist, a doctor, they would have gotten that message; correct?
A. Yes.
Q. Okay.
A. With patients.
Q. Now -- were you finished?
A. Well, yes. If you hear about a recall drug, it's a recall drug.
Q. All right. Fair enough.
A. The people who are -- a recall drug is a recall drug, but there's a change in the level of alarm. To some patient populations, it was downplayed. It was removed. But a recall is a recall.
Q. All right. So then would you also agree, from your experience with the FDA, that the FDA approved all recall communications before they were

Page 198

issued?
Would you agree with that?
A. The FDA inspectors were very, very concerned about not having received final copies of the recall letters.
Q. Well, my question is, before these letters went out to the various recipients, is it your understanding -- and maybe you don't have an understanding, but my question to you is, is it your understanding that the FDA would have approved the substance, not just the substance, would have approved in its entirety the press release, the communication to pharmacies, the communication -- any communication that was sent out about the recall?
Is it your understanding the FDA would have approved that?
A. Yes.
Q. Okay. Now, you --
A. I hope that that actually did occur in this case, but I can't -- perhaps I should have gone back in a very detailed analysis, but I don't think there is.
I think there was a concern about the delay in the recall procedures and the delay in providing final reports. But, yes, the FDA should

Page 199

have approved what was released.
(Discussion off the record.)
THE WITNESS: It would be in the May 20th meeting closeout. I'm pretty sure it was the meeting closeout --
MR. DEAN: Thank you.
THE WITNESS: -- because they became --
MR. THOMPSON: This is mine. You gave this to me.
MR. DEAN: You keep it.
MR. THOMPSON: I'm happy to put it back into play, but I don't want to be accused of swallowing a copy.
BY MR. DEAN:
Q. Your criticism on the difference in the communication of information about various groups is set out in your report, is that right, on the recall communication?
A. Yes.
Q. Do you remember the substance of that -- of that?
A. It's in this document. I mean, I was asked specifically to comment on certain issues, particularly the change in renal insufficiency to renal failure.

Page 200

And that's where I made the question that that could be an artifact of the review of something being written to a fourth- to fifth-grade level.
I don't know about press releases to the general public, whether they have the same requirements as the informed consent to clinical trial.
So we talked about that with the renal insufficiency. We talked about the removal of the once daily dosing.
And then I brought up the third change in the -- in the press release, because the Health Hazard Assessment said lack of efficacy with exacerbation, and that was omitted.
So there were three changes, daily dosing, renal insufficiency and lack of efficacy were distilled down to renal failure.
Yes, you're correct, that could have been done in negotiations with the FDA. In light -- in light of that FDA document that says there was no risk to public health, there may be background to this.
But there were three changes. And it does change the direct communication to the patient

Page 201

population at risk.
Q. Let me hand you what we marked as 37.
A. Okay.
MR. DEAN: Fred.
BY MR. DEAN:
Q. Have you ever -- have you seen Exhibit 37 before?
A. Yes.
Q. Okay.
A. This was -- this was the basis on which I tracked -- I was asked to track the changes and comment whether there were change in the populations described from one communication to the next.
Q. And one of these communications went out on April 25th; is that right?
A. Yes.
Q. And can you direct us to that?
A. That's 28213. That's the press release.
Q. And is it your understanding that that was issued on April 25?
A. Yes.
Q. And --
A. I cannot comment at this point in time the relationship between this release and the FDA approval or any impact of the FDA review on the

Page 202

changes.
Q. Now, your point is, if I understand, the point -- the basic point in your report is that on this April 25 press release, it mentioned a renal failure, and several days later different communication was conveyed to pharmacies; is that correct?
A. Well --
Q. Is that one of your basic points?
A. I have this packet of communications.
Q. Right.
A. I have nothing else. When one stops a clinical trial such as the WHI, there are letters that go out to the doctors, the patients, the study coordinators.
I do not know whether that is a standard in a drug recall like this. These are two different situations.
Q. Right.
A. But I don't have any letters directly to patients or directly to doctors. I have only this.
Q. Okay.
A. I have a Health Hazard Assessment, I have a communication to Mylan, which never, to my knowledge, reached the public except in this exhibit,

Page 203

and then there's a press release that went out.
So I was asked specifically to comment on the changes from A to B to C, and what the patients and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall.
Q. Okay. So --
A. But there was granularity omitted from the press release and the question is why.
Q. Right.
And so when you said A to B to C, A would be -- the first thing in the sequence would be the press release on April 25; right?
And then what is B and C in terms of your last answer?
A. The press release was on the 28th. The internal communication to Mylan was on --
Q. Excuse me. The press -- or the news release --
A. I'm sorry. The Health Hazard Assessment was the 28th. Is -- no, the 18th. The Health Hazard Assessment was the 18th. I think it was sent over on the 25th. The cover letter was the 25th.
Q. Okay.
A. The press release was also on the 25th.

Page 204

Q. Right.
And then --
A. And then the internal letter went out subsequently. Now, I would have -- I don't know about the receipt date. I think the cover letter -- you can check the cover letter on the Health Hazard Assessment.
Q. We will in a minute.
What was the follow-up -- there was a follow-up letter that I think you referenced in your report after the press release. Was it the Dear Valued Customer letter?
A. That's the 28th. That's an internal communication.
Q. What's the Bates number page there, Dr. Frank?
A. It's 28208.
Q. So in the April 25 press release, it simply references renal failure.
But in the April 28 Dear Valued Customer letter, it talks about patients taking daily doses or patients with renal insufficiency; correct?
A. Yes.
Q. And you believe that's more detailed information that was not contained in the press

Page 205

release; correct?
A. Well, it is more detailed. But it changes the population at risk. So the press release -- and this is where I was -- I was asked to comment on certain things.
I was asked to analyze evidence to support two observations when I was asked to do this.
One was the systemic issues of pharmacovigilance on signal detection and the other are these changes from one to the next. And that's what I did.
I'll admit, this wasn't sequential. This actually was a later date than the press release. I will -- yes, you're correct on that.
Q. Which is -- which is -- what date is on that?
A. This is the Dear Valued Customer.
Q. Right.
A. And I questioned what the customer was, and I was told that was internal. That did not go out to the patients, to my knowledge.
Q. And so what you're suggesting is, I think, that the company had information on April 25 that it didn't put in the press release that it did put in the April 28 letter; is that correct?

Page 206

A. Yes. The internal communications show a broader patient population at risk than the communication to the public.
Q. And you said that while the -- before you mentioned that while the Health Hazard Evaluation report was done on April the 18th, you said it -- I think you said you were right that it was transmitted on April the 25th; correct?
Is that your recollection?
A. There should be a cover letter. And, as I recall, it's the 25th, and I went, why did it take so long to transmit something that was written on the 18th? But the April 18th is something I reiterated in the document.
Q. Well, your memory is actually very good, Doctor.
I'm putting in front of you Exhibit 220 --
A. Yes.
Q. -- which is that cover letter from Dr. Leikin's group to Sarita Thapar; correct?
A. Uh-huh.
Q. And it's dated April the 25th; correct?
A. Yes.
Q. And can you -- and for the record, how

Page 207

was that letter sent?
A. Overnight Federal Express. So it arrived on the 26th.
Q. So it arrived on the 26th; correct?
A. Yes.
Q. So on April the 25th, when the press release was issued, the information in the Health Hazard Evaluation had not been received, had it?
A. Unless there was an additional faxed copy and this was the follow-up hard copy.
Q. And -- but you -- again, that's an area where you don't have information; correct?
A. No. And I did not -- I knew that letter was the 25th, but I -- I did not connect the fact that the press release went out the day before that would have been received if that was the only copy.
Q. And can we also agree that in the Dear Valued Customer letter, the information in here about the two groups, about the daily dosage group and the renal insufficiency group, that is contained in the Dear Valued Customer letter on the 28th, isn't it?
A. I need to look at this again before I answer.
Q. Sure. Take your time. It's 28208.
A. 28208.

Page 208

(Witness reviews document.) It has toxicity -- daily doses or renal insufficiency, and it contains the lack of efficacy. Yes, I think this one tracked verbatim to the Health Hazard Assessment.
Q. So this, the Dear Valued Customer letter, tracked the information contained in the Health Hazard Evaluation report that was transmitted to Actavis on April 25 by Federal Express; correct?
A. Yes.
Q. Okay. But you didn't -- when you were doing your review, you didn't link that up in your mind, did you?
A. I think I was operating on the assumption that that press release was made after receipt of the Health Hazard Assessment or communication of what was in the Health Hazard Assessment.
And that may have been because I made assumptions that I -- when I received this assignment, I was asked to reply on a series. And I did not go back.
I looked at these dates and I wondered why that cover letter was dated the 18th, during -- the 25th and why the Health Hazard Assessment was the 18th, but I didn't go back and verify this. I -- and

Page 209

I don't know.
They may have issued the press release before they got the Health Hazard Assessment based on some sort of a preliminary analysis. Perhaps that company internal document that I have not seen.
Q. But from what you have seen and what we have in front of us, anyway, today, when they issued the press release on the 25th, they would not have had the Health Hazard Evaluation; correct?
A. Unless there was a copy faxed in followed by the FedEx.
Q. Okay.
A. I actually -- I do not have documentation of what the supporting documents were for that press release.
The assumption was that the Health Hazard Assessment from the 18th would have been wrapped up into external communication for just these issues.
But that -- that cover letter does beg the question because it would have been received one day after the press release.
Q. At the bottom of Page 6 -- I'm back on Exhibit 261, Dr. Frank.
The bottom of Page 6 there is a -- the

Page 210

second sentence says there was a notable absence -- I think you left out the word "of" -- absence of oversight from a centralized headquarters function in Iceland to track local compliance and exchange of information between the U.S. and the EU affiliates.

What is the basis for that opinion?

A. Okay.

Q. First of all, what documentary -- what documents do you have that are even relevant to that issue?

Let's talk about that first.

A. That's why there's an absence.

One of the things the health authorities do in these drug withdrawal cases, for new adverse events, say liver failure or torsade, if the health authority identifies the issue before the company, they go back to the company and say, why are we telling you about a serious safety problem with your drug?

The assumption is that the company should have processes in place to identify the issue first, and then go back and tell the health authority it exists, and then the issue starts into a dialogue of whether this drug has to come off the market.

This is conventional wisdom. And I

Page 211

didn't -- I don't want to document the cases where this occurred.

But when I've worked at headquarters, these international companies typically are headquarters holding companies, and each country level affiliate is an independent company under the holding company, and they operate in conjunction with local regulations.

Headquarters typically tracks compliance at the local level. But the responsibility is there.

But there's a growing movement toward tracking this data, spidering this data from local departments onto dashboards of managers.

And so the issue here -- and I talked to them, this is somewhat outside of my expertise, but my question is, I was given no evidence that headquarters identified these noncompliance issues before the FDA 2008 inspection.

So the remediation was to do new processes, to move things to Elizabeth, to make a provision that Copenhagen would send cases to the U.S.

But I have no evidence that headquarters was actually -- had a strong governance function over the individual compliance.

They didn't realize that Copenhagen was

Page 212

stockpiling reports and sending them in July and August when the implementation date on that MHRA agreement was March 1st.

That could have easily been picked up by tracking those dates, those submission dates.

And so the question comes up, and this is -- this is, again, extrapolating from other cases where the authorities come back and say to the company, why are we telling you about these issues?

Q. Well, let's stop. First of all, it sounds like you raised with the plaintiffs' lawyers the issue as to whether you had expertise to even comment about this issue; is that fair?

A. Well, we talked about scope, and I'm talking about systems. And this is on the edge of those systems because I have some experience. I've never done a merger integration.

I was involved with Roche headquarters drug safety reorganization, which was clearly a headquarters reorg. where there was centralization of procedures that had been decentralized, gone out of compliance.

And it's the centralization and headquarters oversight that has frequently been critical in these multinationals that have compliance

Page 213

issues with safety, not just with Roche, but with other companies.

Q. Did you tell the plaintiffs' counsel in this case this was outside your area of expertise?

A. I asked if they thought it was and whether I should take it out and they were pleased with that being left in the document.

Q. But you, yourself, raised the question as to whether it was outside your area of expertise; correct?

That's what I hear you saying. I want to make sure I understand you correctly.

A. Well, this is my first time as an expert witness, and I'm trying to determine what scope of pharmacovigilance systems is. This is -- this is technically within the scope of --

Q. I know. My question was -- I'm sorry.

A. It may be, but I can't give you a definitive answer.

Q. My question was very simple. Did you tell the plaintiffs' attorneys this was outside your area of expertise?

A. It was possibly.

Q. Okay. Now, you don't know how Actavis in Iceland was set up structurally to interact with

Page 214

Actavis in the United States, do you?
A. No. We were not given any information as to the headquarters function and overseeing their affiliates or how much headquarters was initially involved with the 2006 inspection, other than to ratify the decision at the time of the acquisition to implement the MHRA agreement between the two.
Q. Is it fair to say you have insufficient information to be able to comment on the oversight responsibilities of headquarters in Iceland in regard to local pharmacovigilance issues?
A. These may have been placed. I was not given any information to say that there were. And I don't -- I don't know I do.
I know that they wanted -- when they got the first inspection, the initial fix was to move the processes to Actavis.
There's not a lot of insight into the process of transfer or any other process changes at the time of the acquisition and the merger of some of these acquisition companies.
I guess, there is -- there's an absence of insight into what happened. There's no assurance.
Q. Do you consider yourself to be an expert in the issue of recall communications?

Page 215

A. Honestly, no.
Q. Okay.
A. I can't say that I've done a huge number of them.
Q. Okay. And I think we established before that what you did in regard to recalls was maybe do the Health Hazard Evaluation reports. But you've never participated in drafting the recall documents themselves; correct?
A. No. My role has been to draft the assessment -- my role has been to draft the assessments. And sometimes I sit on the multifunctional team.
But once the decision is made to recall or to try to obtain product for analysis, typically, any recall communications go out of a different office.
MR. DEAN: All right. Let's take a short break.
VIDEO OPERATOR: Going off the video record.
The time is 3:19 p.m.
(A recess was taken from 3:19 p.m. to 3:30 p.m.)
VIDEO OPERATOR: We're now back on the

Page 216

video record.
The time is 3:30 p.m.
BY MR. DEAN:
Q. Do you have any criticisms of the information gathering process for information that would go into a MedWatch report by Actavis before the time of the recall?
A. There are inspection observations from the inspection of January 2006 that there was inadequate information in the cases and inadequate follow-up, and they cited several cases.
So they were looking at the content of information, things that were absent, such as concomitant medications and concurrent diseases, as well as follow-up issues, particularly on a death case.
Q. Are you aware of any -- let me reframe my question in point of time. Same question, but after January 3, 2007, when the letter that we saw was issued.
And so after January 3, 2007, are you aware of any criticism -- and before the recall, in that time frame from January '07 to end of April, '08, are you aware of any criticisms of the information gathering process by which Actavis gathered

Page 217

information to generate MedWatch reports?
A. No.
Q. Okay. Did you ever say to the plaintiffs' attorneys in this case that I cannot in good conscience give an expert report in this litigation because I am concerned that I don't have all the potentially relevant documents?
A. I said I do not think I can render a definitive opinion. I can only give opinion on the evidence to which I was -- on which I was presented.
And I talked to them about what if I render an opinion that's inadequate based on inadequate evidence? And they encouraged me to render the best opinion that I could based on the evidence that I was presented.
They presented me with some more evidence, and I did the best I could with what I was given.
And I knew that there were vulnerabilities that remained based on white space, but there was -- there was -- the original report was written with more statements of no assurances provided, no information is provided.
There was more of a statement of the absence.

Page 218

I was asked to rephrase things to say, my opinion based on reasonable evidence, and I did that on June 15th.

So there was a report written that was -- with language where I would be presenting this to a client based on a consulting firm.

And I was given some guidance on how to rephrase the report, and I went in and I rephrased the report where I thought there was FDA inspection observations that would fit together as reasonable evidence, such as I keep repeating, the fact that 2008 still had inspection findings.

It was a question of nonsubmission of cases. There were things like that that became the basis.

But I actually trusted them that they were providing me enough information that it was conscionable to form those positions.

They reviewed them and they reviewed the final wording, and I trusted their counsel that this report, although preliminary and possibly requiring revision, was suitable for filing.

Q. Now, did you just tell me that there is a -- I guess it would be on one of these thumb drives -- that there is an initial report that you

Page 219

wrote and then there's a follow-up report that you wrote after you had expressed concerns to the plaintiffs' counsel about what you'd said in your report?

Did I get that correctly?

A. No. I was very, very careful about making too many preliminary comments. I spent an awful lot of time trying to gather and organize the information and track it.

I probably started tracking quality information from manufacturing and trying to assess whether the quality systems were impacting pharmacovigilance. I probably went on a tangent.

But, no, there was no real preliminary report that I revised. I did the report and I was asked to change the wording to the legal wording required for an expert report.

Q. Now, is the backup to what you just said where you were -- where you made changes in the wording, is that someplace on the thumb drive?

A. I don't know whether I overwrote it. I think there are early drafts.

Q. You used the word "conscionable" a few minutes ago.

Were you worried as a matter of your

Page 220

conscience that you might be rendering an opinion without appropriate foundation?

Was that what you meant to convey by your use of the word "conscionable"?

MR. THOMPSON: Object to the form.

THE WITNESS: I'm completely naive to this. I've avoided this for eight years and I was encouraged to write this report based on people who had worked with me who felt that I was qualified to start to take on this kind of work.

I have no way to independently judge my ability to serve as an expert witness. And I don't know whether this is the type of case where you start expert witness.

I trusted the attorneys who provided me with information to give me the information that I needed to determine what was going on.

I went back to them with questions and I did ask about the process of discovery and why there were all these things that I was not provided and would they be provided to me. And I talked to them about what do I do with this information?

And they -- she said -- based on that, I believe that it was okay to render the preliminary report. I did this on advice of counsel and with the

Page 221

supervision of counsel.

But knowing that there could be further information that may or may not have been already uncovered with discovery.

And I was told that it is okay to render this preliminary opinion. If they present you with further evidence, you go back and revise it.

BY MR. DEAN:

Q. Is it fair to say that based upon what you've seen today, you are no longer comfortable and you do not stand fully behind this opinion?

A. I would say yes. My preference would be to, as I was told I could do, incorporate new information.

But -- but, yes, there -- I -- I think that there has to be -- there should be re-analysis of that opinion based on further information. And maybe even some of the information that's not yet presented.

Q. So is it fair to say that as from your -- with your medical training and your background in the FDA, you, yourself, think that there is an inadequate foundation for your opinion in this report; correct?

A. I don't have an answer to that. I feel -- Mr. Thompson encouraged me at the break to say,

Page 222

well, you're as much an expert on this as anyone else.
I have no way to compare myself to anyone else. I've never even witnessed court proceedings. I deliberately avoided getting involved with litigation. It's not like I've been aiming at this.
This is something that I was approached about doing a couple times and sort of said, no, no, no, I'm not going to be involved with that.
And I was approached about taking this assignment and very carefully working on it. I asked about the documentation.
And I had to trust the people who had hired me that I was being given correct guidance so that this would be a useful piece of information and a viable one, but I have no way to independently judge that.
If -- I should have said, I cannot write this report until I am given all of this, I was given assurance that I'm to render a preliminary opinion based on what was given me.
Q. So it was your understanding that what was submitted to the Court was just a preliminary report, then; is that right?
A. It was my understanding that these

Page 223

opinions were to be based on observations that I could make based on the present state of the evidence provided to me. I was asked not to say anything speculative.
I asked Pete Miller specifically about this comment about the headquarters oversight, and he liked that comment. He did not ask for it to be written.
But I asked, I said, is this -- I don't know -- I can't give you the exact wording, but I wanted to make sure I didn't go out of the scope.
But I was extrapolating these pharmacovigilance systems which usually go into a headquarters oversight.
And he particularly liked that section of the report, and I was given no indication that the inclusion of those statements would be a problem. He approved them.
Q. So I understand that particular exchange, you raised the question about your expertise to give an opinion in that area, and Mr. Miller's response was, I like that opinion. Let's leave it in.
That was the conversation; correct?
A. I don't recall the specifics.
Q. Is that the --

Page 224

A. I don't recall. I don't recall whether I --
Q. Is that the --
A. I don't recall whether I pressed him on how far I should extend out. I know they've encouraged me several times not to go outside of the scope of my assignment in making comments.
But that statement was included in the conclusion with Mr. Miller's approval.
Q. How do you think all this impacts on your credibility, Dr. Frank?
A. I think it demonstrates a very legitimate attempt to do a decent job with suboptimal information. If I did not know to refuse to render an opinion, then I wish I had been informed by the counsel.
But I think it demonstrates my ability to analyze the quality of the evidence and to define things that could potentially be missing. Some of the things that you presented to me I would not have known to even have asked for.
But I raised the issue of whether or not these opinions should be rendered on a series of evidence, and I was given no indication that this was unconscionable or would be seen to jeopardize my

Page 225

credibility.
It may display a learning curve. It may display a naivete at dealing with certain things. But I was never once given any indication that this was unconscionable or unethical behavior.
Even though I questioned, I wanted to make sure that none of this was done, and we discussed it on June 2nd. This is a pretty complex case.
There's a lot of stuff that was not -- was not -- I don't know -- I don't know whether it should or should not have been prepared for me, whether it was incumbent upon me to go find the additional information.
I asked for more. Or whether I should have quietly made a determination on the first dossier.
Q. But we can agree, in your words that you uttered two minutes ago, that the information you had here on which to base your opinion was suboptimal; correct?
A. Yes. It was suboptimal. There's -- there was probably a lot more information out there that was not present.
Q. And information which might well lead you to change your opinion; correct?

Page 226

A. Modify the opinion, yes.
MR. DEAN: Let's end this tape.
VIDEO OPERATOR: Going off the video record.
This is the end of Tape 4.
The time is 3:46 p.m.
(A recess was taken from 3:46 p.m. to 3:50 p.m.)
VIDEO OPERATOR: We are now back on the video record.
This is the start of Tape 5.
The time is 3:52 p.m.
BY MR. DEAN:
Q. Dr. Frank, do you realize that there's a lot of money at stake in this litigation?
A. Yes.
Q. And do you realize there are Court-imposed deadlines for all of us, expert witnesses and lawyers?
Do you realize that?
A. Yes.
Q. Were you led to believe that this report that you were going to -- that you have submitted was only a preliminary report?
Was that the indication that you were

Page 227

given?
A. I'm afraid so.
Not -- the word "preliminary" was not used, but I was led to believe that there would not be any question or problem writing this in this way, and that if I was presented with additional evidence, I was to modify this.
And I -- Mr. Thompson is concerned that I've suddenly backed away from my report because I've been presented with two pieces of evidence.
I'm sorry, maybe I'm just frightened. I don't want to do anything wrong. And maybe I need more assurance than the average person.
But, yes, I did realize there was a deadline. I was a little amazed when I found out that this was actually going to be a big federal case. I thought it was a rather small assignment. But he's concerned that I backed down too quickly.
I don't know how to gauge accurately what is sufficient information to render -- completely render opinion.
I may have -- I asked many people whether I was qualified to do this as an expert witness. He's asked me to stand by what I said.
But, yes, one of the reasons I sit here

Page 228

and I examine what you said -- give me very carefully is I realize there's a lot at stake. And I want to be careful to do the right thing.
I was -- I thought that I was being careful enough. And he wants me to stand by what I've written.
Q. Were you --
A. I'm -- I'm sort of like, this is the first time I've done it, I want to make sure that it's done absolutely correctly.
And yet, I can tell you right now that I started going through this and going, well, I mean, I can tell you that there was other information that would have given indication of the compliance.
But I said, well, they still had inspection findings in 2008. That probably indicates inadequate implementation of the plans.
So I've been -- I've sort of been encouraged to, even though I may be naive and a little bit insecure in what I'm doing, stand by this.
Now, I just -- I just don't want to do anything wrong. I did the best I could with what I was given, and I worked under the guidance of my client.
Q. Your client being the plaintiffs'

Page 229

lawyers; correct?
A. Knowing that you would come with further evidence. And how I should respond, he said, well, look, you're backing down. You've been shown two additional pieces of evidence. Is that enough to sway your whole opinion?
I'm sitting here, well, I guess I'd like to do another careful analysis. But he's encouraging me to stand by my opinion.
Q. What I'm interested in is whether you are willing to stand by it given what you have seen today.
And I get the impression that you are -- you don't think that there is a sufficient -- I get the impression you think there's not sufficient information base for you to continue to stand by this opinion.
Am I correct in that impression?
A. I actually don't know how to answer you.
Q. You can't unequivocally stand behind the opinion that you have written, can you?
A. No.
Q. Okay.
A. But I don't know that it should be discarded.

Page 230

Q. You said that --
A. I actually was under the impression that if I was presented additional information, I was to modify the position to accuracy and that there would be no problems whatsoever in taking this course.
Q. You told me a few minutes ago that there was other information that you had that would have led to the conclusion of compliance with appropriate procedures, but you did not put it in your report.
Why didn't you put it in your report?
A. Can you tell me what I omitted? Can you give me the specifics of what I said?
Q. I'm just referencing what you said a few minutes ago, that there were -- if necessary, we could have the court reporter read your answer back.
But I believe you said that there were -- there's other information that was available that would have aided the defendants -- that's not quite the way you phrased it -- but there's other information that would have led to a different conclusion but you left it out of your report.
Do you remember saying that?
A. No. I never deliberately omitted any opinion -- any evidence that would have swayed the opinion in the direction of the defendants. There was

Page 231

no attempt to deliberately omit information.
I did not put into the report all of the verbal communications, such as the -- all of the Digitek cases would have arisen only in the U.S.
Q. Do you --
A. But I never specifically said I'm not going to put this in because it will change the opinion in favor of the defendants.
I never would have done something that could have led to that kind of discredibility or lack of credibility. There was none of that. And that I can give you a definitive answer of no.
If I forgot to put something in, it was an error or I did not realize that I was to put in verbal information.
I did put information in of inspection findings of compliance with product complaints. I had the interim information for product complaints that you showed me for safety.
But it was actually an inspection confirmation, and that's in here. And I put it in because I thought this would be one report with some -- the conclusions to support. But I did not deliberately omit any information.
Q. Could you tell me -- you just referenced

Page 232

information about product complaints. Could you tell me what -- if you can find it, what page you're referencing, Dr. Frank.
If you can't find it readily, that's okay, just tell me. But if you can find it, I'd like to look at that page. I realize there's a lot of pages.
A. No, I think it's important because I tried to find both. I tried to find as much information as I could.
(Witness reviews document.) I saw it a while back.
(Witness reviews document.)
Q. Let me do this. Let me see if I properly understood your reference, and if I did, maybe we don't need to find it.
I think what you said was there was some information that you picked up and referred to in the observations about product complaint information that was appropriately reported.
Is that what you said?
A. It was an inspection finding that said the remediation for product complaints, there was -- there were no observations with product complaints. And this was probably in 2008.

Page 233

Q. So, then, that would probably be in the 2008 EIR someplace?
A. (Witness reviews document.) Yes. Here.
Q. What page are you on, Doctor? I've got a copy here.
A. 28.
Q. Thank you.
And can you direct me to where you are?
A. Inspection 5, Little Falls, New Jersey, 18th of September to October.
And I summarized the only thing I found in that was the Establishment Inspection Report, under the general discussion, complaints were reviewed, there were no deficiencies found.
I have no ability to assess the impact of the sampling of the complaints in this inspection and the direct impact on Digitek.
There was a supplemental document that showed -- and there was -- there's a comment from the FDA in here, that the compliance with 30-day timeline for product complaints improved over the course of 2007 to the point of the inspection.
Q. And we have talked before about the fact that one thing you would like to see is the product -- in the course of investigating a product defect, would

Page 234

be good communication between the product complaint side and the signal detection side.
Do you recall that discussion?
A. Yes.
Q. And so what you're saying, I think, is that, at least from this observation on Page 28, that as of 2006, the product complaint side appeared to be functioning appropriately; correct?
Is that the appropriate --
A. I don't know what the scope of that is. Complaints review. Did they just look at the complaint files?
I spent some time trying to assess whether every complaint had an accompanying Health Hazard Assessment.
And what I ended up putting weight on was the FDA observation, because they had access to the information in 2008. They were concerned about the lack of ongoing Health Hazard Assessments.
And in order to get through all of the, I want to say, lack of evidence and confusion, because I couldn't completely sort that out.
And I spoke to them about this, that to base my opinion on the FDA inspector who looked at the primary evidence, even though I did not have the

Page 235

access to it.
So that's where I can't come -- I can't reconcile that with the FDA inspector's concern in 2008 that there were no accompanying Health Hazard Assessments.
I don't know what the overlap was, whether they were fine here and then there were a problem. I can't tell you that.
Q. And this is another manifestation of the fact that you were not provided the underlying documents; correct?
A. I would assume so, yes.
Q. Okay.
A. Or I wasn't given any other Health Hazard Assessment other than the one from Dr. Leikin. I had no documentation of any Health Hazard Assessment in 2004. I asked for it. And I looked for them.
And I had -- the FDA -- the thing that became the basis of the opinion was that inspector -- FDA inspector in 2008 and their concern with the absence of them.
Q. Having heard everything you've heard today in the sense of being shown documents, additional documents today, having gone over all the documents we have in front of us, having gone over

Page 236

your report, having, you know, engaged in the dialogue with me today, do you feel that you have been misled by the plaintiffs' lawyers regarding the factual basis for your opinions?
A. I don't know how to comment on that. I thought that I got a dossier that was not in chronological order.
I wasn't sure that I got the full component of the documents. I wasn't sure that the full components had actually been discovered on part of discovery.
I cannot say I was deliberately misled, particularly because -- I don't know how to answer that.
I had to assume that if they wanted me to write an expert report to be filed in this case that they would take a lot of care to provide the best documentation possible.
I can't rule out bias, but I'm -- I have to say that that's not my point to assess. Perhaps I should not have made an assessment about the discovery, but I was surprised by the sampling of the evidence.
I thought I would get everything so I'd be able to track things out. That may be my

Page 237

misunderstanding on what is adequate evidence.
Q. Are you --
A. And my -- is it my inability to render opinion on what is adequate evidence that is the core of the problem? Or do I rely on the people who provide it to me to ensure that this is adequate for the opinion that I render?
Q. But you would agree that this is a troubling issue given the lack of information that you had?
A. I think it's a -- yeah, I think it's -- I think that -- yes, it does bother me.
Q. And at the end of the day, having, again, looked at all the documents, engaged in all the dialogue that we have, are you still willing to continue to serve as an expert witness on behalf of the plaintiffs in this litigation?
A. My number one concern in this situation is that I don't do anything considered wrong or I don't have problems with the fact that I'm new to this and I will have to learn certain things.
But I don't want to do anything that would be considered incorrect.
Now, I agreed to do this. I communicated my concerns. There's an interest for the

Page 238

plaintiff in my standing by my opinions.
I have little or no interest in going into a public deposition before a panel of judges and finding that -- I have to -- I don't -- I don't want to destroy myself.
I asked if I was -- you know, if I was considered too lightweight a witness to hold up this case. I have no way to independently judge that.
But it's extremely important that my level of expertise is sufficient to hold the weight. Even if this is an opinion that doesn't support eventually.
But I have no -- I have no way to independently judge whether I am truly an expert witness. What does that constitute?
Is it a few people saying you are, we want you to do this? We've done it. There may be another expert witness who's asked to critique your work.
But I've not been led to believe that, given my present abilities or knowledge, that pursuing this is foolish, unethical. I can't say that I've been led to believe that.
And yet, it's my strength of ego to say to you, yes, I will stand by this and I will argue and

Page 239

argue.
And yet, I have doubts about -- I can't say I've done this five times successfully and, therefore, I've demonstrated my ability. I can say that I've been encouraged to pursue this and to submit this document.
And I've made certain, as I'm doing this, by asking for external confirmation that I've not been doing anything foolish or incorrect.
Q. Knowing that there is a lot of money at stake, knowing that there are court rules in place for expert reports, knowing that expert reports have to have appropriate foundations, my question to you is, are you willing to continue as an expert witness in this case?
A. The honest answer is, I never wanted to have to sit expert witness in court. That was not disclosed to me at the time I agreed to do this. I agreed to write a report and sit deposition on the report that I made, on the evidence I was given.
Q. Are you telling me that you weren't told that you might have to testify in court? Is that what you're telling me?
A. That was not disclosed to me when I agreed to do the engagement.

Page 240

Q. So to the extent -- you've now learned that; correct?
A. Yes.
Q. Correct?
So to that extent, you were misled; correct?
A. The --
MR. THOMPSON: Object to the form.
THE WITNESS: The preliminary communication from the consulting firm is they had received a request for somebody to do an expert witness on pharmacovigilance systems.
And I asked what that would entail. And they said, you'll be sent evidence and you try to come up with a truthful answer. And you'll have to sit deposition. But --
BY MR. DEAN:
Q. Excuse me. Mr. Thompson actually gave a good objection there because -- let me rephrase that question.
Do you feel you were misled by Smart Consulting about what your role was going to be in this litigation?
A. I was led to -- the -- what I agreed to do would have stopped at the end of today.

Page 241

I did not agree to sit expert witness before a panel of federal judges, and then I found out even later that Pete Miller wanted me to be a witness in the actual litigation in November.
These things were sequentially disclosed to me, and my level of comfort with my own inexperience and not knowing how to gauge my preparedness was real.
Q. Is it fair to say that you would have declined this assignment if you had been told at the beginning that you would have to testify in court before a jury?
A. I never really wanted to get into this line of work. I was led to believe this was a very limited assessment. I was not aware at the outset that it was a bunch of state litigation that had been rolled up into a federal case.
There was -- there was no up-front communication of the extent of the work or the high-profile nature of the case or -- and I had no assessment of my potential impact on the outcome.
I don't know whether I'm a small fish or a big fish in the outcome. I can't say that.
Q. We can agree, though, that you were not told at the outset that you would have to be a

Page 242

testifying witness in court?
You were not told that; correct?
A. No.
Q. You were -- no, you were not told that; correct?
A. No, that was not disclosed at the outset. There was sort of a sequential disclosure of increasing levels of involvement.
Q. When was it that you were finally told that you would be asked to testify in court before a jury?
A. I don't know the exact date, but I believe sort of about the time I had lunch with Pete Miller. It may have been a phone call, it may be at the June 2nd lunch.
But -- and I didn't know whether he was making this assessment to bring me further in the case based on his preliminary interactions, whether this was a change in plans, or whether -- or how this all occurred.
I can't judge -- I really -- I don't want to judge his motive. I just know there was a sequential expansion of this.
Q. When you -- I said -- before you mentioned that I think you were drafting a report on

Page 243

June 15th.
As you were drafting on June 15th or thereabouts, at the point where you were writing this long report, did you understand you were going to have to testify in court?
A. Possibly, yes. Yes. Yes.
Q. Possibly or for sure?
A. I -- I was told that, in all likelihood, I would be asked to present at the science day.
Q. At the science day?
A. Which is October.
Q. Were you ever told that you would be -- have you ever been told that you would be asked to testify in one of the individual actions?
And by that I mean a case in which one of the plaintiffs is suing the defendants to try to obtain a money judgment against the defendants.
Have you ever been told that you would be expected to testify in one of those cases?
A. I was told that they may ask me to appear in November, in a November case. In all likelihood, I would be.
And -- oh, no, I do understand liability. No. I understand the magnitude of this. I understand what rolling up a bunch of state-level

Page 244

litigation is. And I understand -- no, I understand -- I understand what this is.
I just wish I had -- this may be a self-confidence issue with me. I don't know how to gauge my preparedness. I may be completely prepared. I may be very good at this, but I can't tell you whether I am or I'm not.
Q. But you do wish that it had been disclosed to you much earlier that you were expected to testify in front of a court or jury; correct?
A. Yes. I would have preferred my first expert witness assignment to be limited in scope so that there was an assurance of the accuracy and the success.
That the magnitude of this case and that the questions that I raised about the discovery and what was being sent to me had not arisen. You know, maybe I'm out of line as an expert witness saying what about the discovery?
I assumed that all of these blank documents, these white spaces, would be sent to me.
When they told me that they weren't sure they already had them and they may be able to obtain them, because there may be one more round of discovery, I just went -- be as -- technically, if I'm

Page 245

-- I thought I should have everything to track through the period and maybe track from the consent decree.
But I don't -- I can't tell you I'm right or wrong based on experience.
Q. Dr. Frank, is it fair to say that you have significant misgivings about your ability to qualify as an expert witness and you have significant misgivings about the quality of the information that supports the opinion that you have written here?
Would that be fair to say?
A. I hate to say significant misgivings because I've been assured that -- I've been given assurance that moving forward with doing this I would not have embarrassment or problems.
Q. And who has assured you that you would not have embarrassment in the future as we move forward in this litigation?
A. The people at Smart Consulting, Nigel Smart and Denise Smart.
Q. And what did he tell you? Tell me what assurance -- how did he articulate this assurance that you would not be embarrassed as we moved forward?
A. Well, he said, really all you have to do is try to get to truth. We're just seeking that. And on the evidence presented to you, you try to sort out

Page 246

what truth is.
And I got to a situation where I was like, I became concerned that I hadn't been -- I didn't have all of the communications.
I didn't have -- I didn't have anything to confirm -- I just got the FDA -- I was asked to make the determination only on the FDA inspections and some letters. The letters say we're going to do this.
I don't have the details of what was done or the tracking that showed that it was done.
And this is stuff that typically is given to consultants when they go in and assess vulnerabilities to repeat inspections. And I asked about it.
Q. So is it fair -- is what you're saying, there might be a basis for the opinions you've given, but you're not sure because you haven't seen the evidence? Is that what you're saying?
Isn't that a fair summary?
A. Yes. I can assure you that I did the best that I could with what I was given. And I based it heavily on a few FDA observations from point to point. But there's interim space where I don't have a lot of insight into what went on.
It's the FDA inspection, the

Page 247

communications, and the confirmatory inspections.
MR. DEAN: Thank you.
Give me just a minute, Fred.
VIDEO OPERATOR: Going off the video record.
The time is 4:23 p.m.
(Discussion off the record.)
VIDEO OPERATOR: We're now back on the video record.
The time is 4:24 p.m.
MR. DEAN: I do not have any more questions on behalf of Actavis.
EXAMINATION
BY MR. KAPLAN:
Q. Dr. Frank, I'm Harvey Kaplan.
A. Yes.
Q. I've been listening to your testimony here today. I want to ask you a few questions.
You've rendered the opinions contained in your report; right?
A. Yes.
Q. And those are all of your opinions?
A. Yes, they are. I reworded them to say it is my opinion based on reasonable evidence, and I did this on June 15th.

Page 248

And I looked at it, and I said to myself, I hope that in rewording these statements I actually have -- am making it on what is considered reasonable evidence.
That I was provided the reasonable evidence and I can trust that, and that I was able -- this is -- I was provided huge amounts of documents about manufacturing and analytical issues.
But there was a question in my mind about what was reasonable evidence in this case? Do I have to go through every CAPA tracker?
And I do want to make sure before this is actually admitted that I don't want to let my insecurities, which could just be me -- I might have simply done an analytical analysis.
But, yes, I -- these opinions were there. I can't see that a lot of things that would typically have been done have been done.
I was asked -- I was asked to support certain opinions that counsel wanted supported. And so what I did was took the evidence and I couldn't see anything to the contrary.
If I had had a clean inspection in 2008, I would have said, the evidence for adequate remediation is the inspection from 2008. Now, he

Page 249

subdivided the inspection.
Did you see evidence in 2008 that they did not remediate the quality of the reports? So the -- there may be overgeneralizations. But they may be legitimate on -- for certain grounds.
Q. So you were given direction by plaintiffs' counsel as to certain opinions they wanted you to express?
A. He said I would like to say that there were systemic issues that impacted, and I believe it was the safety signal detection in the Digitek case. I was actually presented an opinion by counsel.
I wasn't sent the dossiers without -- I was told the opinion that I was asked to support to the best that I could. And I did attempt, and you see there's things that are included here that really sort out what actually happened.
Q. Plaintiffs' counsel said to you these are the opinions we want you to express?
A. Yeah. They asked me to go through and support certain observations.
Q. And you attempted to support those opinions that you were asked to express by plaintiffs' counsel; right?
A. Yes.

Page 250

Q. And you have expressed all of those opinions in Exhibit 261; right?
A. The answer to that is, I cannot tell you because I thought these two were going to go together.
Q. Okay. This is your report, Exhibit 261; right?
A. This was split off. This up until maybe it was mid-afternoon, I'd have to look, on the 15th, I thought I was submitting all of this together. So that there was a much careful tracking between the observations and my comments.
So my concern is that since this was split, I never did an independent assessment of a hundred percent transfer of every single opinion in here to here. There was just sort of a high-level overview.
Q. And what we have been presented is the report of Karen A. Frank, M.D., dated June 15, 2010, as contained in Exhibit 261, which you have entitled Background, Analysis and Conclusions; correct?
A. Yes. It was segments --
Q. And Section 3 is called Analysis and Conclusions; right?
A. Yes.
Q. And your conclusions are all expressed

Page 251

in Section 3 of Exhibit 261?
A. Yes.
Q. Correct?
A. Yes.
Q. Okay. And what I'm wondering as I listen to you talk today about evidence that wasn't given to you before you prepared this report by plaintiffs' counsel, and that you have only learned about in the last day, specifically Exhibit 38, the FDA's statements on their web site about Facts and Myths About Generic Drugs, and other evidence has been presented to you today that you have discussed with Mr. Dean, what I'm wondering and what I'm concerned about is, are you still willing to walk into a court of law, raise your right hand and be sworn to tell the truth and to stand by with confidence the opinions that you have expressed in Exhibit 261?
MR. THOMPSON: Object to the form.
THE WITNESS: I'd prefer to have substantially more evidence before I had to do that. You're leading me to believe through your line of questioning that I have formed opinions on what is not considered reasonable evidence.
Now, if I led you to believe that, because I'm raising questions, was I remiss in raising

Page 252

questions about the process of discovery and what was presented to me? Have I led you down that path?
But you are leading me to believe that what I have is a sampling of documents that I could be asked to determine whether that is reasonable evidence, and I may or may not know the real answer to that.
BY MR. KAPLAN:
Q. Here's the bottom line. You agreed to act as an expert witness in this litigation; right?
A. Yes.
Q. You're being paid for your services; right?
A. Yes.
Q. You've been asked to render opinions; right?
A. Yes.
Q. You have rendered those opinions; right?
A. Yes.
Q. And this is our opportunity to test those opinions.
A. Yes.
Q. To test the basis for those opinions.
You understand that?
A. Uh-huh.

Page 253

Q. You have to say --
A. Yes.
Q. And it is our opportunity to determine whether or not there is a reasonable, scientific basis for the opinions which you have expressed.
Do you understand that?
A. Yes.
Q. And that's what we are doing.
A. Yes. There is risk in these opinions because they were based on there is not evidence provided. So there are opinions that are based on the absence of the evidence.
Q. Which is why I asked.
A. No, I'm not comfortable with that.
Q. Okay. And that's why I asked you.
The next step would be to walk into a courtroom here in Philadelphia with a federal judge heading up the Multi-District Litigation, the judge in charge of the Pennsylvania consolidated litigation, the judge in charge of the West Virginia litigation, the judge in charge of the New Jersey litigation, and the judge in charge of the Texas litigation, and for you to walk into that courtroom, be called as a witness and to get up on the stand and to testify in front of that court of law and render these opinions,

Page 254

and say to these judges under oath that you express the opinions that are contained in Exhibit 261 to a reasonable degree of scientific probability that these are correct and that you, as a medical doctor, who has worked for various pharmaceutical companies and for the FDA, can say with confidence that you stand behind those opinions.

Are you willing to do that?

MR. THOMPSON: Object to the form.

THE WITNESS: Should I discuss this with you?

MR. KAPLAN: No. Just answer my question.

MR. THOMPSON: I think that the question is on the floor.

THE WITNESS: I really don't want to, but I'm concerned about the fact that it's just that I only wanted to do the preliminary background work, the supportive work, and end with a private deposition like this.

When they told me I had to go to court, I was like, this is a huge issue. I'm completely naive with this, and I don't know how to judge my preparedness.

And I most certainly -- the most

Page 255

important thing is, I don't want to do anything that would be considered wrong.

If I've gotten into something where the work product is inadequate, he's concerned that I'm backing down based on the presentation of two or three pieces of evidence. And I'm at a loss to know the right course of action.

I'd prefer not to testify in a high-profile case. If I do, I'd like to make certain that I'm presented everything. I was actually led to believe that if you presented me with more evidence today, this would be revised.

And I'm concerned about that, because that would allow me to go through this if they found more information and make sure everything was correct.

BY MR. KAPLAN:

Q. This is it. This is our opportunity to examine you on the report that you have given --

A. I know.

Q. -- in the Multi-District Litigation that's pending in Charleston, West Virginia, and in the Pennsylvania consolidated litigation, which is pending here in Philadelphia.

There are about a thousand cases that are riding on opinions of expert witnesses here like

Page 256

yourself.

A. Yeah.

Q. And what I want to know is, whether you're willing to stand behind these opinions and go into a court of law and to say with confidence, the opinions you've given here today, that you stand by these opinions, as a person of integrity?

A. You have both led me to believe that there's additional evidence that I was not presented, even though I asked for it. And proceeding forward, I could face significant embarrassment, if not questioning, of the opinions.

And the whole time I did this, I tried to document very, very carefully. And yet, you're leading me to believe that this is a great embarrassment and that I've done an inadequate job and I can't support what I've done.

He doesn't think I should back down. And the only thing I can think of is I don't want to do anything wrong.

Q. What do you think you should do?

A. I would like to -- if I could, I would like to stop with only doing background supportive work.

Q. Well, let me say that that's not the

Page 257

option right now.

A. It's one or the other?

Q. Yes. Either you go forward or you back down.

A. What if I choose not to go forward? What are the implications?

Q. That's up to you. You can say, I withdraw as an expert here. I'm not comfortable with it.

A. But what are the implications of that? Will I be in a lot of trouble?

Q. You won't be in trouble. You just won't be an expert in this litigation.

MR. THOMPSON: Well, I am going to object and I am going to say that this would be something that I would view as something that would -- I would be entitled to confer with the expert witness about is that question about withdrawal.

THE WITNESS: Okay.

MR. THOMPSON: Certainly you can question her about the report. You can question her about the documents. You can question her about all that.

But I believe that I would have an opportunity to confer with her about that issue of

Page 258

whether she would continue employment or not.
BY MR. KAPLAN:
Q. What do you want to do?
A. The right thing.
Q. What do you think that is?
A. The safe thing is to withdraw. If at this point I can withdraw and there will be no questions that I've done the best I could and there's tremendous -- there may be more risk to everyone if I proceed.
You're basically saying that if at this point there's question that putting me on a witness stand can be an embarrassment or jeopardize the litigation, then the right thing to do would be to withdraw.
But I hope I could do that without being accused of doing anything wrong. I would hope that people would say she did the best she could with what she was given and under the guidance she was given.
But I have been so frightened -- when I say frightened, since I started this, that I would do something wrong and there would be consequences, that this could just be my fear because I'm naive to this.
I've stayed away from it even though people have encouraged me to get into it.

Page 259

And I just -- I don't want to do anything wrong where there would be consequences for me, even to question my credibility. That's my number one concern.
And I may have to say that I did something -- I was told -- I keep being told to have self-confidence. But right now, I don't. There's significant concern.
And, of course, you would want me to not be a witness for the plaintiff. I guess the fewer there are, I just don't want to do anything wrong. And I'm actually scared to move forward.
I can probably put this together and pick through all of the statements.
I was able to answer Mr. Dean when he asked me about the 2007 letter and say, well, corrective actions imply there was something wrong that had to be corrected. I can make the analysis.
But you're leaving open to me a question of the wisdom of it and of subjecting my client to unnecessary risk in a court of law because I'm not necessarily strong enough to stand up to it when they feel that I am and a few other people do.
So I'm willing to say, well, I've done something, I have learned.

Page 260

But at this point, I didn't know that this was such a heavy assignment when I agreed to do it, and I didn't feel that I should withdraw when they told me this when they felt I was strong enough.
But now I'm being seriously questioned, and I would have preferred to have this be a limited assignment and to not jump right into a very big case.
As you said, there's very, very high risks. There's no way I can assess the real risk. And all that I can think in my head right now is I just don't want to do the wrong thing.
And that's what I did for two to three weeks when I took this assignment.
I just don't want to get into anything that's wrong, that I can't do appropriately. That's my only concern.
Q. Well, my concern and Mr. Dean's concern is that our clients are being accused of wrongdoing.
A. I'm not trying to do that.
Q. And our clients are being accused of selling and distributing --
A. Oh, your clients. Oh, I'm sorry.
Q. -- defectively manufactured Digitek.
A. I was thinking the law firm. I trusted their counsel. I thought you were asking me -- no, I

Page 261

take that initial response back.
Q. I want you to understand this is very serious business.
A. It's very serious.
Q. Millions of dollars are being sought from our clients.
Do you understand that?
A. Absolutely.
Q. And --
A. I'm not that naive. I'm not --
Q. Plaintiffs are offering expert testimony, like your testimony, to support their case.
Do you understand that?
A. Yes. I do understand. I know what this means. I know what's at stake.
Q. To support their allegations of wrongdoing against our clients.
You understand that?
A. Yes.
Q. And that's what you're doing in this case.
A. He asked me earlier whether I was a witness for the plaintiff or a truth seeker. And what happened when I started asking for more information was, I'm -- I became more of a truth seeker.

Page 262

I told you this. I don't know how much this all supports directly the Digitek case.
I never saw information that subset the direct impact on Digitek. I can only make generalization statements. And I hope they aren't wrong generalizations. There is more evidence to be obtained.
Q. And you certainly never saw any evidence that any person received defectively manufactured Digitek, did you?
A. No.
MR. THOMPSON: Objection. Asked and answered.
BY MR. KAPLAN:
Q. Did you?
A. Well, I was told this would be asked. Now, what I know is that there were an influx of cases after the recall was announced. I have not been given any of that evidence. That was sent to someone else.
Q. So what I'm saying to you is --
A. I haven't.
Q. -- you've never seen any evidence --
A. No.
Q. -- to support an allegation that any consumer ever ingested defectively manufactured

Page 263

Digitek, have you?
A. No, I've not been provided that. I've been provided evidence -- evidence that says that it's worth being investigated further. But I've not really been able to investigate it further.
Q. And you're a person who worked for and was trained by the FDA?
A. Yes.
Q. You had good training at the FDA?
A. I thought it was very, very good.
Q. Quality, competent people?
A. Yes.
Q. You have faith and confidence in the FDA?
A. Yes. I'm -- I'm -- I do understand all of the issues with other litigation. It's not my point to comment here.
This issue of how far I was to comment on this assessment has come up. I was told that leaving this comment in about the headquarters oversight was okay.
Q. Just follow me. Follow me here for a little bit.
And being a person who worked for the FDA, who was trained by qualified and competent people

Page 264

at the FDA, and who places great reliance on the integrity of the FDA --
A. Yes.
Q. -- you do that, don't you?
A. Yes.
Q. And you have testified that in the opinions you've rendered, you relied upon FDA inspection reports --
A. Yes.
Q. -- and what the FDA inspectors have said?
A. Yes. Solely. I am relying on their assessment of the primary data.
Q. And so, after all is said and done, after all of these inspections and after all of your reliance on what the FDA inspectors have said with regard to the primary data and after the recall, we come full circle, do we not, to Plaintiffs' Exhibit 38, which you were shown today?
A. Yeah.
Q. Right?
A. Uh-huh. Yes.
Q. Okay. And that's entitled Facts and Myths About Generic Drugs; right?
A. Yes.

Page 265

Q. And that's a statement of the FDA; right? Correct?
A. Yes.
Q. And it's a very important statement of the FDA, isn't it?
A. Yes.
Q. It speaks directly to the Digitek recall, doesn't it?
A. Yes.
Q. And it is a statement to the public about the Digitek recall; right?
A. Yes.
Q. The myth, as expressed by the FDA on Page 2, is that there are quality problems with generic drug manufacturing. They characterize that as a myth; right?
A. Yes.
Q. And they further say, as to the myth, A recent recall of generic Digoxin (called Digitek) shows that generic drugs put patients at risk.
The FDA says that's a myth; correct?
A. Yes.
Q. And under Facts, the FDA says, In our best judgment, given the very small number of defective tablets that may have reached the market and

Page 266

the lack of reported adverse events before the recall, harm to patients was very unlikely.
That's what the FDA says is a fact; correct?
MR. THOMPSON: Object to the form.
THE WITNESS: That was my concern when I started asking questions of is there any information that I can have that would tell me how -- what is the percentage of any given batch affected, and what is the chances that multiple pills ended up in one bottle?
BY MR. KAPLAN:
Q. And now you have seen the FDA's statement as to this Digitek recall, haven't you?
A. Yes.
Q. And the FDA continues to stand by that statement, don't they?
A. Yes.
Q. They haven't changed it since the recall, have they?
A. No, not -- not on June 15th.
Q. And so we come full circle; correct?
A. Well, at this point, I have no information on Digitek, per se, of any safety signal detection. I can't tell you, and I have -- I raised

Page 267

this, and that's actually in my comments.
The issues with the pharmacovigilance system are broad. There was an absence of signal detection during the 2004 to 2006.
If the FDA looked into that and there is nothing else that would refute this statement, I will never be able to refute it even if given the evidence.
And if you say that the FDA has already done that, and said that, then, you know, I can sit here with the evidence. I will just be confirming this.
Q. This is the FDA's bottom line statement as to Digitek, isn't it?
MR. THOMPSON: Object to the form.
THE WITNESS: Yes.
BY MR. KAPLAN:
Q. You believe the FDA, don't you?
A. Yes.
Q. And this is the information -- this is part of the information that was never disclosed to you by plaintiffs' lawyers, isn't it?
A. And I did not seek it independently.
Q. This information, Exhibit 38, the FDA's statement --
A. No.

Page 268

Q. -- as to Facts and Myths About Generic Drugs, and their specific statements about Digitek, were never revealed to you by plaintiffs' lawyers, were they?
A. No. And I will say --
Q. Were they?
A. No. I did confirm when I took this case that all that I was required to do is to seek to come to truth. And that's all that I had to do.
Q. And do you believe that the FDA's statement in Exhibit 38, statements that I just read to you, are the truth?
A. Yes.
MR. KAPLAN: Thank you very much.
MR. THOMPSON: I'm going to have some questions. I understand Mr. Moriarty objects to my asking questions, or at least he did the other day.
MR. KAPLAN: Well, Mr. Moriarty isn't here.
MR. THOMPSON: Well, I'm going to ask a few questions.
EXAMINATION
BY MR. THOMPSON:
Q. Doctor, let me ask you to look at Defendant's 38.

Page 269

Do you have that in front of you?
A. Yes.
Q. You have been asked and your attention has been directed to one sentence in paragraph four of five bullet items.
Do you see that?
A. This right there (indicating)?
Q. Yes.
A. Okay.
Q. Do you see that each time you've been asked about this document, your attention has been directed to the second sentence of bullet line item number four?
A. Yes.
Q. Let's go back up and ask you to read the entire bullet item of number three, bullet item number three.
A. Although Actavis attempted to remove the affected Digitek tablets through visual inspection, FDA determined that this method of removal was inadequate to assess the product's quality and consistency, in accordance with GMP regulations, good manufacturing -- current good manufacturing practice, parenthesis, CGMP regulations.
Q. Now, read the entire bullet point number

Page 270

four for me.
A. Since the detection of the manufacturing problem, FDA has been actively engaged with this company to ensure that all potentially infected lots have been recalled.
In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to the patients was very likely (sic).
Q. Now, do you believe that the FDA's judgment with regard to its determination of violation of good manufacturing practice would be as authoritative as that that you just answered Mr. Kaplan?
MR. DEAN: Objection to form, and also lack of expertise on inspection procedures, which she's already testified to.
MR. KAPLAN: I join that objection.
THE WITNESS: No. I had no way to come up with this conclusion that the FDA came up with because I had no information.
It was redacted out of the documents and I wasn't provided access to any information on analysis of the batches. I still think a lot was

Page 271

incinerated.
And there was no data mining of the database. We're assuming that when the FDA read this, that they were satisfied with the case reporting. They did not go back and re-data mine that database.
BY MR. THOMPSON:
Q. Did you --
A. But I don't know. I have an absence of information.
And it's affecting -- it's clearly affecting my security at standing here and saying yes or no, because what I've been asked to render is very generalized, and I would prefer to have access to the remainder of that information.
Q. All right.
A. If, indeed, this is the bottom line, then I'm concerned that even if I asked for all the information, I won't come up with a different answer.
If this above there says, well, nobody ever looked at the lots before they ended up on the market and, therefore, this unlikely is based on, well, we never looked at the lots, that's what he's implying, that there is some uncertainty to that.
And now the question is, can I actually say -- because I'm not a GMP expert and I know nothing

Page 272

about how to quantitate abnormal pills and lots, I can't tell you what procedure they should use.
Q. Doctor, let me ask you a couple questions.
Do you know what period of Digitek drugs were recalled, for what time period?
A. It started June 6th, 2006, and I believe went for two years, up until the May -- or the April -- the date of the release of the recall. But I did look at that.
And I tried to sort it out because it had to do with -- it wasn't manufacture date, it was market release date.
Q. All right.
A. And I did take time to sort that out and then I was sort of out of scope.
Q. All right. Well, let me ask this: When this FDA facts and myths document was posted, was Digitek being made available to consumers in the United States?
A. When this was posted, I don't know what date it was posted. And I don't know whether Digitek was still in the market. I can't answer that. I was unable to find the date when he asked me for it.
Q. Well, if, assuming that the bullet point

Page 273

says lack of reported adverse events before the recall, can you date this as to when it was vis-a-vis the recall?
A. The recall package was dated April 25th, 2008. So it was up until that point. It was -- it was -- the press release was the 25th of April.
So you can say that up until public awareness of the recall on the 25th that there was no impact of the recall on the reporting rates.
So that the reporting rates up until the recall were not induced reporting rates. That as soon as that press release went out, the increase in reporting rates was significantly influenced by the knowledge of the recall.
And I cannot comment because I haven't looked at the cases. This is someone else.
Q. All right.
A. How many of those were potentially frivolous cases and how much were concerning -- how many cases do we have of documented supratherapeutic digitalis levels, how many cases took the tablet.
I do know that you can see digitalis toxicity at therapeutic doses. You don't have to be supratherapeutic to have the toxicity.
So it makes it very, very difficult to

Page 274

sort out based on clinical symptoms whether you're dealing with supratherapeutic digitalis.
And I was very thankful that I did not have to render an expert opinion on that, that you probably took doctors who were experts in digitalis.
Q. All right. That actually raises a question.
Is an adverse event report, is that voluntary or mandatory at the clinician's level?
A. In the U.S., it's voluntary.
Q. If a practicing physician had a patient who showed symptoms of Digoxin toxicity, would that, as a common practice, generate an adverse event report?
MR. KAPLAN: Objection. Calls for hearsay.
THE WITNESS: Well, that's difficult to say.
With a drug that's as old as Digoxin and as established, I can tell you right now that there are hospital admissions for digitalis toxicity. That when I was a resident I was not aware of MedWatches.
BY MR. THOMPSON:
Q. All right.
A. The issue when you're in a drug company

Page 275

is that a post-marketing report in most companies defaults to possible.
By virtue of the fact that the person had a clinical suspicion, when it's reported to the company, when you do that relatedness assessment inside the company, many big pharma SOPs default to possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.
So they default to submission to the FDA. There is some variability, but my understanding is the industry standard for post-marketing, when it's unsolicited, defaults to possible.
Q. All right. Let me ask you to look at Defendant's Number 20. I think it's on your -- it should be on your stack there.
No? It should be --
MR. DEAN: This is a stack here, I was trying to get it organized. Let me find it for her.
Here you go.
BY MR. THOMPSON:
Q. All right. You were shown -- I'm going to hand you Defendant's 20. You were shown this summary of findings of the CGMP inspection.
Do you recall?
A. Yes.

Page 276

Q. You recall -- I think your testimony was you had not seen this before?
A. No.
Q. Okay. Now, what's the date of the CGMP inspection?
A. December 1st, 2004.
Q. All right. Is there any date, is there any operative date, that's been involved in any question that you've been asked that includes 12/1/2004?
A. No. However, the investigation report for the double-thick Digitek tablet was July 2004.
Q. All right.
A. I'm not sure what date. But it was five to six months before this repeat inspection.
Q. All right. And do you know the date of production of this document to the plaintiffs in this case?
A. No. I do not know whether this was inadvertently omitted from my packet, whether it was in the millions of pages, some -- and not sent to me or whether it was sent to the plaintiffs late, and, therefore, we have evidence after I was submitted my dossiers --
Q. All right.

Page 277

A. -- that I should be allowed to consider as later evidence.
Again, this is -- I keep saying my naivete and maybe it's just my foolishness to say my naivete. But there may be issues with this. There may be late discovery that I would be permitted to review without any embarrassment.
Q. All right. Now, let me ask you to pull out the big -- the attachment to your report.
MR. DEAN: Excuse me.
If we're done with that, let me get that one back in the stack of exhibits so it doesn't get misplaced.
MR. THOMPSON: Thank you.
THE WITNESS: I did ask --
BY MR. THOMPSON:
Q. The big appendix. The big appendix.
A. Yes. I did ask if there was going to be more discovery, if discovery was complete, if all of these documents had been obtained, and if I could request these missing documents in discovery, and they said there may be that chance.
Q. All right.
A. And I was led to believe that it was permissible to proceed in such a manner, that as a

Page 278

witness, I was allowed to question this and ask for more information.

And that if I was provided it, that I could modify my report based on the submission of new evidence to me.

That filing that report would not embarrass me, the Miller form, or Motley Rice, if another round of discovery would produce new evidence.

Q. Okay. Let's go to Page 20 and 21 of that attachment.

A. Okay.

Q. Now, there in the middle of the page of Page 20 there is a lengthy quotation.

A. Yes.

Q. You see that? What is that quotation from?

A. It's from Reference 4 on Page 2. And Reference 4 is the August 15th warning letter based on the company response of February 28th.

Q. And what day is that?

MR. DEAN: What year?

MR. THOMPSON: Yes.

BY MR. THOMPSON:

Q. What's the date?

A. August 15th, 2006 warning letter based

Page 279

on the company response dated February 28th, 2006.

So what happened with the 2006 inspection is the company sent a response on February 28th to the 483, and then again on February 28th. And the FDA sent a revised warning letter and had concerns.

Q. All right.

A. Yes.

Q. Now, let's go to Page 21.

A. Okay.

Q. And you have a comment on the following page --

A. All right.

Q. -- where you relate the -- and maybe I should just get you to read it. If we go down one, two -- the sentence that begins In light of.

Do you see that?

A. Yes. Should I read the entire paragraph?

Q. Just read out loud the sentence that begins with In light of.

A. In light of the FDA 483 inspection observations from May 20th, 2008, it is my opinion based on reasonable degree of evidence that the compliance remediation in 2006 was not adequate either

Page 280

in content or in implementation to remediate the inspection findings of delinquent expedited reporting, inadequate case follow-up, or the quality of reports.

Q. Okay. Now, if I hand you Defendant's Exhibit 87, which you saw for the first time today during the -- and I'll just hand you my copy of it, which you saw for the first time today, and you indicated that was one of the three documents that caused you to worry about your -- the quality of your opinions.

Do you see that?

A. Yes.

Q. And you agree that that's the letter that caused you to question that; is that right?

A. Yes.

Q. Okay. Read me the two sentences back to back.

Well, read me the entire second paragraph.

A. New Jersey District has reviewed your response regarding the Adverse Drug Experience reporting deficiencies. Your corrective actions and the revised procedures appear to be satisfactory.

We will, however, confirm the adequacy of your corrective actions and assess the overall ADE

Page 281

reporting system during a future inspection.

Q. Okay. Now, what do you think the last sentence of that paragraph means?

A. They will confirm the implementation, the adequacy of the implementation. At this point it appears they're okay with the content.

They will confirm the adequacy of the implementation and they will expand the confirmation, not just to the adequacy of the directed corrective actions to the observations in 2006 --

Q. Okay.

A. -- but they will expand this to include the adequacy of the entire ADE system.

Q. All right. Now --

A. This --

Q. Let me ask you a question.

A. Okay.

Q. I want to go back to your comment at Page 21. Okay.

Now, do you stand by your opinion that was expressed on Page 21 that taking the findings of the 2006 inspection and taking the findings of the 2008 inspection that the compliance remediation was not adequate either in content or implementation to remediate the inspection findings?

Page 282

MR. DEAN: Objection.
MR. KAPLAN: I'm going to object and ask for some clarification. I was told, I thought it was her sworn testimony, that Exhibit 261, that all of her opinions were contained in Section 3 entitled Analysis and Conclusions of Exhibit 261?
THE WITNESS: But I also stated that this document was split in a very short time frame and there was a chance that not all of them were completely transferred. I believe this is in 261.
MR. KAPLAN: Well, I'd like to have the reference to it because I'm trying to -- what I was trying to do is figure out what are your opinions.
And I looked in the analysis section, and I'll just tell you that I looked for words such as it is my opinion that or it is my opinion based on the evidence that.
And I counted, starting on Page 5, going through Page 9, seven -- seven opinions that you expressed in there. And so I did the best I could.
Following that, I asked you the question are all your opinions contained in 261. Your answer was, yes, you relied upon that.
So I just don't understand what it is we're being asked to do here to try to suck out

Page 283

opinions from another document that in your opinion --
MR. THOMPSON: This entire document was produced timely. It's been in your possession. I'm sure you've had people analyzing it. And the words have been in your possession for --
MR. KAPLAN: So you're telling me that not all of her opinions are in Exhibit 261 --
THE WITNESS: I modified this.
MR. KAPLAN: -- the June 15, 2010 document prepared by Dr. Karen A. Frank, entitled Background, Analysis and Conclusions, that's not all of her opinions?
We have to go searching beyond that; is that right?
MR. THOMPSON: I don't know that you have to search. All you have to do is read it.
MR. KAPLAN: Well, I've read this and I've tried to sort out her opinions, and whenever she expresses an opinion she says it is my opinion that and I've relied upon that.
And that's where I get seven opinions, so I don't understand where else. This is not a game.
THE WITNESS: I have this -- I have this on Page 5, paragraph three, the last sentence.
These observations, taken in their

Page 284

entirety, provide evidence that the pharmacovigilance system and the accompanying quality systems remain inadequate to ensure compliance with regulatory reporting or requirements of the compliance remediation, either from the MHRA inspection of 2005 or the FDA inspections in the first quarter of 2006.
I did not go into the specifics of the single-case reporting or the narrative quality. I would have to go back and verify that.
But the -- when this really became a pressured situation to make a determination, I relied very, very heavily on this 2008 inspection to show that there were persistent observations that were not remediated.
I couldn't say whether it was the content of the plan because I wasn't provided that, or the implementation. Because it could be a bad plan with good implementation or it could be a good plan with bad implementation.
MR. KAPLAN: If there were remediation problems, do you think the FDA would have said in Exhibit 38 that there was a very -- it's very unlikely that anybody was harmed as the result of defective Digitek?
MR. THOMPSON: Let me interrupt. It

Page 285

sounds as though we're going to go a little more than five minutes and he -- I think we're running out of tape.
VIDEO OPERATOR: We have one left.
MR. KAPLAN: Will you answer that question?
MR. THOMPSON: Have I passed the chair to you?
No, wait. Go ahead. Go ahead. Go ahead.
MR. KAPLAN: Okay.
MR. THOMPSON: Go ahead.
MR. DEAN: First, we need to change the tape.
VIDEO OPERATOR: Going off the videotape.
This is the end of Tape 5.
The time is 5:11 p.m.
(Discussion off the record.)
(The court reporter read back the following:
"QUESTION: If there were remediation problems, do you think the FDA would have said in Exhibit 38 that there was a very -- it's very unlikely that anybody was harmed as the result of defective